In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-43V

Filed: August 14, 2018

CAYLEE HARRINGTON,	*	
	*	PUBLISHED
Petitioner,	*	
v.	*	Special Master Oler
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement; HPV, Gardasil, multiple sclerosis (MS).
Respondent.	*	
	*	

Glynn W. Gilcrease, Jr., Law Office of Glynn W. Gilcrease, Jr., PC, Tempe, AZ, for Petitioner.

Darryl R. Wishard, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

This is an action in which Caylee Harrington ("Petitioner") requests compensation under the National Vaccine Injury Compensation Program ("the Program").[2] Petitioner alleges that she suffers from multiple sclerosis ("MS") as a result of receiving a second Human Papillomavirus ("HPV" or "Gardasil") vaccination on January 19, 2011. For the reasons set forth below, I conclude that Petitioner is not entitled to compensation.

[1] Because this Decision contains a reasoned explanation for the action in this case, I intend to post this Decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2012)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to redact medical or other information, that satisfies the criteria in 42 U.S.C. § 300aa-12(d)(4)(B). Further, consistent with the rule, a motion for redaction must include a proposed redacted decision. If, upon review, I agree that the identified material fits within the requirements of that provision, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Vaccine Program"), Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. PROCEDURAL HISTORY OF THIS CASE

Petitioner filed her petition[3] on January 17, 2014, alleging that her HPV vaccination of January 19, 2011, caused her "systemic lupus erythematosus."[4] Petition at ¶¶ 2, 8, ECF No. 1. This case was initially assigned to Special Master Laura D. Millman. ECF No. 2. Petitioner filed medical records on June 9, 2014 (Exhibits (Exs.) 2-22, *see* ECF No. 10), and June 24, 2014 (Exs. 23-24, *see* ECF No. 11).

A. Case Development to Clarify Issue of Onset of Petitioner's Symptoms

Special Master Millman held a status conference on August 19, 2014, during which the parties primarily discussed the onset of Petitioner's symptoms in this case. *See* Order of August 29, 2014, ECF No. 14. Petitioner's then-counsel[5] stated that, according to Petitioner's mother, Petitioner "began experiencing symptoms, including fatigue, in late February 2011." *Id*. Special Master Millman, however, observed that the petition and the medical records filed to that date indicated that Petitioner's "symptoms began in April 2011." *Id*. (citing Petition at ¶ 5; and Petitioner's medical records at Ex. 9 at 16). Accordingly, Special Master Millman, among other things, ordered Petitioner and others familiar with the issue of onset of Petitioner's symptoms to file affidavits in this case. *Id.*

Petitioner filed her affidavit (Ex. 27) on November 13, 2014, concurrently filing affidavits

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[3] Caylee Harrington filed a separate, but substantially similar petition on March 14, 2014, which was docketed as case number 14-212V, and assigned to Special Master Hamilton-Fieldman. *Harrington v. Sec'y of Health & Human Servs.*, No. 14-212V, 2014 WL 1813284 (Fed. Cl. Spec. Mstr. Apr. 16, 2014). On April 16, 2014, Special Master Hamilton-Fieldman dismissed case number 14-212V, referencing Ms. Harrington's instant pending case as a basis for case number 14-212V violating the Vaccine Act's requirement that "[o]nly one petition may be filed with respect to each administration of a vaccine." *Id*. at *1 (citing § 300aa–11(b)(2) of the Vaccine Act).

[4] Petitioner originally filed her petition on January 17, 2014, alleging that her HPV vaccination of January 19, 2011, caused her "systemic lupus erythematosus." Petition at 1-2, ¶¶ 2, 8, ECF No. 1. That petition also states that, since her HPV vaccination of January 19, 2011, Petitioner "has been diagnosed with systemic lupus erythematosus, Sj[ö]gren's syndrome, transverse myelitis, complex migraines, and multiple sclerosis." *Id.* at 2, ¶7. Apart from her alleged systemic lupus erythematosus diagnosis, however, the petition did not attribute any of her other conditions to the vaccination. *See generally id.* at 1-3. Although Petitioner did not formally file an Amended Petition to change the specific injury she now alleges was caused by her HPV vaccination of January 19, 2011, the six expert reports filed on her behalf by Lawrence Steinman, M.D., exclusively claim that she suffers from MS due to her allegedly causal HPV vaccination. *See generally* Exs. 35, 40, 42, 44, 46, 47. Petitioner's Pre-Hearing Brief also explicitly acknowledges this change in her alleged injury in this case, stating in the introduction of her Pre-Hearing Brief, "The [P]etitioner, Caylee Harrington, submits this brief in support of her claim that the Gardasil vaccine she had on January 19, 2011, caused her MS, definitively diagnosed in 2012." Petitioner's Pre-Hearing Brief at 1, emphasis added, ECF No. 78 entitled "Petitioner's Opening Brief."

[5] Petitioner has had three counsel of record changes through the pendency of this case, with her current counsel representing her since August 17, 2015. *See* ECF No. 35; *see also* Notice of 8/17/2015, documenting Petitioner's Consented Motion to Substitute Counsel for her current counsel of record.

from her mother, Catherine Harrington (Ex. 28), and her boyfriend, Michael Collier (Ex. 29). *See* ECF No. 20. On December 22, 2014, Petitioner filed affidavits from her treating family nurse practitioner, Teressa Becker, Family Nurse Practitioner (FNP) (Ex. 30), and treating counselor, Julie Nicholson, Licensed Professional Counselor (LPC) (Ex. 31). *See* ECF No. 22. Petitioner subsequently filed a statement of completion on January 21, 2015, indicating the record of this case was complete. ECF No. 23.

Special Master Millman held a status conference on February 4, 2015, to once again discuss the issue of onset. *See* Order of February 4, 2015, ECF No. 24. She reiterated that the medical records filed up to that point indicated an onset timeframe of April 2011. *Id*. Thus, she ordered Petitioner to file a status report "listing citations to any medical records that are dated between January 19, 2011 and October 30, 2012." *Id*. The parties additionally discussed the revelation that Petitioner also filed an affidavit in a related Vaccine Act case -- case number 14-212V[6] -- in which she averred that the onset of her symptoms began in *March 2011*, whereas her affidavit filed in this case (Ex. 27) stated that her onset was in February 2011. *Id*. Accordingly, Respondent requested leave to file Petitioner's affidavit from case number 14-212V -- a request Special Master Millman granted.

On February 5, 2015, Respondent filed a document entitled "Respondent's Status Report And Notice Of Filing" (hereafter "Respondent's Status Report of February 5, 2015") in which Respondent stated that "the medical records indicate an onset of [P]etitioner's symptoms beginning in about mid-April 2011."[7] *See* Respondent's Status Report of February 5, 2015 at 1. Moreover, that status report highlighted the discrepancy between Petitioner's affidavit in this case -- indicating that her symptoms started in "early February 2011" (*id.*, citing Ex. 27 at 1) -- with an affidavit filed in case number 14-212V, in which Petitioner stated that her symptoms developed after mid-March 2011 (*id*. at 2). Respondent concurrently filed the affidavit from case number 14-212V as Ex. A. *See Id.* at 2; *see also* Ex. A ("Affidavit of Petitioner, dated March 13, 2014"), ECF No. 25-1.

In compliance with Special Master Millman's Order of February 4, 2015, Petitioner filed a status report on February 24, 2015, listing citations of all the medical records that are dated between January 19, 2011 and October 30, 2012.[8] *See* Petitioner's Status Report of February 24, 2015, ECF No. 26. On March 6, 2015, Petitioner filed a letter from her primary care doctor, Rachel

[6] *See* footnote 3, *supra*, for a detailed discussion of case number 14-212V.

[7] In support of his assertion, Respondent highlighted several of Petitioner's medical records reflecting Petitioner's contemporaneous complaints to her treating physicians of her symptoms starting in mid-April 2011. *See* Respondent's Status Report of February 5, 2015 at 1 (citing: Ex. 3 at 1-3, 13-21; Ex. 2 at 20; Ex. 5 at 57; and Ex. 9 at 16).

[8] That status report listed the following medical records as being dated between January 19, 2011 and October 30, 2012: Ex. 2 at 5-35; Ex. 3 at 1-33; Ex. 4 at 1-13; Ex. 5 at 1-60; Ex. 6 at 1-12; Ex. 7 at 1-33; Ex. 8 at 15-70; Ex. 9 at 16-20; Ex. 10 at 1-6; Ex. 11 at 1-12; Ex. 12 at 1-6; Ex. 13 at 1-31; Ex. 14 at 1-7; Ex. 15 at 18-28, 30-56; Ex. 16 at 5-43; Ex. 17 at 1-3; Ex. 22 at 1-8. *See* Petitioner's Status Report of February 24, 2015 at 1-2, ECF No. 26.

Sy, D.O., in which Dr. Sy provides her opinion as to the onset and medical causation in this case. *See* Ex. 32; ECF No. 27-1. Subsequently, Special Master Millman held a status conference on March 9, 2015, during which Petitioner relayed her intentions to consult with an expert for the purposes of procuring an expert report on her behalf. *See* Order of March 9, 2015.

B. Case Development while Petitioner Attempted to Procure an Expert Report

From March 2015 until March 2016, Petitioner attempted to procure an expert report in this case. During that time, Petitioner filed additional medical records on March 19, 2015 (*see* Ex. 33, ECF No. 29), subsequently informing the Court on May 6, 2015, that she had retained a neurologist, Darin Okuda, M.D., to review this case (*see* Order of May 6, 2015; *see also* Ex. 34, ECF No. 30).

On May 11, 2015, Respondent filed his Rule 4(c) Report, stating that "this case is not appropriate for compensation under the terms of the Act" (*see* Rule 4(c) Report at 2, ECF No. 32), and that the "petition must be dismissed" (*id*. at 12). Concurrent with his Rule 4(c) Report, Respondent filed a recent medical research article (Ex. B,[9] ECF No. 32-1), which, according to Respondent, reflected that "there is no association between [the] HPV vaccine and demyelinating conditions, including MS" (*see* Rule 4(c) Report at 11).

From May 2015 until mid-November 2015, Petitioner requested, and was granted, numerous extensions of time to file an expert report. *See* ECF Nos. 33-34, 36, 38-39; *see also* non-PDF Orders of: 6/29/2015; 8/6/2015; 8/28/2015; 9/29/2015; and 11/2/2015. On November 18, 2015, Petitioner filed another motion for extension of time, indicating that she had recently retained the services of Lawrence Steinman, M.D., to submit an expert report on her behalf. ECF No. 41 at 1.

C. Case Development through Expert Report Filings[10]

1. Dr. Steinman's First Expert Report

Petitioner filed an expert report by Dr. Steinman on March 1, 2016 ("Steinman First Rep.", Ex. 35, ECF No. 43-1), concurrently filing the corresponding medical literature cited in that report

[9] Scheller NM, et al., *Quadrivalent HPV Vaccination and Risk of Multiple Sclerosis and Other Demyelinating Diseases of the Central Nervous System*. JAMA. 2015; 313(1):54–61.

[10] In my discussion below, I attempt to elucidate the procedural history surrounding Petitioner's filing of six expert reports from Dr. Steinman. In so doing, I briefly discuss some of the orders filed by Special Master Millman shortly after the submission of each of Dr. Steinman's expert reports, in which she provides her preliminary view of Dr. Steinman's expert opinion. I note, however, that I have *independently analyzed* the entire record of this case, and my analysis in the Analysis section, *infra*, was formulated after my own close review of the medical records, and my own determinations regarding the persuasive value of the expert reports and medical literature filed by both parties.

(Exs. 36-39,[11] ECF Nos. 43-2 thru 43-5).

In response, Special Master Millman issued an Order on March 7, 2016 (ECF No. 44), highlighting the deficiencies she found in Dr. Steinman's first expert report regarding the appropriate temporal relationship between Petitioner's second HPV vaccination and the onset of her symptoms three months later (*id*. at 2-3). She encouraged Petitioner's counsel to "seriously consider making a motion to dismiss her case." *Id*. at 3.

2. Dr. Steinman's Second and Third Expert Reports

On March 8, 2016, Petitioner filed Dr. Steinman's second expert report, responding to Special Master Millman's concerns with his previous expert report. Ex. 40, ECF No. 45-1. Petitioner also concurrently filed the corresponding medical literature cited in Dr. Steinman's second expert report. Ex. 41, ECF No. 45-2. Thereafter, Special Master Millman issued an Order on March 9, 2016, criticizing Dr. Steinman's interpretations of key medical literature cited in his second expert report. ECF No. 46.

In response, Petitioner filed Dr. Steinman's third expert report on March 10, 2016 (Ex. 42, ECF No. 47-1), concurrently filing the corresponding medical literature cited in his third expert report (Ex. 43, ECF No. 47-2).

3. Respondent's Expert Reports

Respondent filed an expert report by a neurologist, Richard Tenser, M.D., on April 20, 2016 (Ex. C, ECF No. 49-1), concurrently filing his CV (Ex. D, ECF No. 49-2) and the medical literature cited in his expert report (Exs. E-O, ECF Nos. 49-3 through 50-6). On that same date, Respondent filed a status report informing the Court that he had also retained an immunologist to provide an expert opinion in this case. ECF No. 51.

Respondent filed an expert report by his immunologist, Harry Schroeder, M.D., Ph.D., on June 27, 2016 (Ex. P, ECF No. 53-1), concurrently filing his CV (Ex. Q, ECF No. 53-2) and the medical literature cited in his expert report (Exs. R-AA, ECF Nos. 53-3 through 54-6).

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[11] For clarity of the record, I note that Ex. 36, entitled "Medical Literature Index," is a list of the twenty-six articles cited in Dr. Steinman's first expert report. ECF No. 43-2. Petitioner's counsel did not properly file, as separate exhibits, the twenty-six articles listed in that Medical Literature Index. Instead, Petitioner's counsel filed the entirety of the twenty-six articles over three separate exhibits -- Ex. 37 (ECF No. 43-3), Ex. 38 (ECF No. 43-4), and Ex. 39 (ECF No. 43-5) -- doing so without proper pagination. Thus, for ease of reference, I will use the page numbers generated from the CM/ECF filing reflected at the top of the page.

I additionally note that Petitioner's counsel filed all of the corresponding medical literature that was submitted with the five subsequent expert reports from Dr. Steinman in this same manner. Moreover, some of the exhibits filed by Petitioner's counsel in this case do not contain proper pagination. *See* Exs. 35-36, 40-44. Accordingly, I will use the same citing convention outlined above for all of those filings.

4. Dr. Steinman's Fourth through Sixth Expert Reports, and Respondent's Responsive Expert Reports

Special Master Millman held a status conference on July 13, 2016, during which Petitioner informed the Court of her wishes to file a rebuttal expert report from Dr. Steinman responding to Respondent's expert reports. ECF No. 55. Special Master Millman granted that request. *Id*.

Petitioner filed Dr. Steinman's fourth expert report on September 6, 2016 (Ex. 44, ECF No. 56-1), primarily rebutting Dr. Schroeder's expert report. On that same date, Special Master Millman held a status conference to discuss Dr. Steinman's fourth expert report. ECF No. 57. During that status conference, Special Master Millman stated that Dr. Steinman's fourth expert report only rebutted the opinion of Dr. Schroeder, but did *not* rebut the opinion of Dr. Tenser. *Id*. Petitioner thus requested additional time to file an expert report by Dr. Steinman rebutting the opinion of Dr. Tenser. *Id.* In turn, Respondent also requested time to file an expert report by Dr. Schroeder, responding to Dr. Steinman's fourth expert report. *Id.* Special Master Millman granted both of those requests. *Id.*

Respondent filed a status report on September 7, 2016, noting that Dr. Steinman's fourth expert report references medical records that were not submitted into the record of this case, and requesting that Petitioner file those records. ECF No. 58 at 1-2. Special Master Millman subsequently ordered Petitioner to file those missing records. *See* non-PDF Order of 9/7/2016.

On October 17, 2016, Petitioner filed the medical records ordered by Special Master Millman (Ex. 45, ECF No. 59-1), and also filed Dr. Steinman's fifth expert report rebutting the opinion of Dr. Tenser (Ex. 46, ECF No. 59-2).

On November 1, 2016, Respondent filed the supplemental expert report of Dr. Schroeder (Ex. BB, ECF No. 60-1), and the corresponding medical literature cited in that expert report (Exs. CC – DD; ECF Nos. 60-2 and 60-3). Subsequently, on November 28, 2016, Respondent filed the supplemental expert report of Dr. Tenser (Ex. EE, ECF No. 61-1), and the corresponding medical literature cited in that expert report (Exs. FF-GG; ECF Nos. 61-2 and 61-3).

Special Master Millman held a status conference on February 15, 2017, during which she ordered Petitioner to file Dr. Steinman's sixth expert report that discussed "the timing of the onset of [P]etitioner's symptoms," and that "provide[d] a basis for any conclusion [Dr. Steinman drew] about causation." ECF No. 62. On April 27, 2017, Petitioner filed Dr. Steinman's sixth expert report. ECF No. 64-1.

D. Case Development since April 2017

On May 15, 2017, Special Master Millman issued a Pre-Hearing Order scheduling a two-day entitlement hearing for February 14 and 15, 2018, and setting filing deadlines for both parties. ECF No. 65. Pursuant to that Pre-Hearing Order, Respondent submitted his pre-hearing

submissions on January 11, 2018, concurrently filing an exhibit list (ECF No. 68), a witness list (ECF No. 69), and Respondent's Pre-Hearing Brief (ECF No. 70).

On January 16, 2018, Petitioner filed a motion for an enlargement of time, informing the Court about the agreement of both parties to waive the hearing in this case, and requesting additional time to file her pre-hearing submissions. ECF No. 71. Special Master Millman granted that request on the same day. *See* non-PDF Order of 1/16/2018. Also on January 16, 2018, this case was transferred from Special Master Millman to Chief Special Master Nora Beth Dorsey. *See* Order of 1/16/2018, reassigning case to Chief Special Master Dorsey.

Chief Special Master Dorsey held a status conference on January 17, 2018, during which both parties confirmed that they agreed to waive the entitlement hearing in this case and requested a ruling on the record. ECF No. 74. In turn, Chief Special Master Dorsey ordered that the parties file a joint status report affirmatively stating in writing their intentions to waive their right to an entitlement hearing. *Id.* Chief Special Master Dorsey also ordered the parties to file a joint pre-hearing submission addressing any factual disputes and identifying "the issues that [the parties] would like [Chief Special Master Dorsey] to address in her ruling." *Id.* Moreover, she ordered that, in the joint pre-hearing submission, the parties: "[S]hall also include a list of the dates and exhibit numbers of petitioner's MRI reports and shall confirm that all of petitioner's MRI reports have been filed." ECF No. 74 at 1. Additionally, Chief Special Master Dorsey ordered that after all of the parties' responsive prehearing briefs were submitted, the record of this case will be closed. *Id.* at 2.

The parties filed a joint submission on January 19, 2018, affirmatively stating that they waive a hearing in this case, and requesting that a determination regarding entitlement to compensation be made based on the existing record. ECF No. 75. Additionally, that joint submission stated the following:

> The parties have little dispute regarding the facts, as the medical records set forth petitioner's relevant medical history. The parties agree that petitioner was diagnosed with multiple sclerosis ("MS") in April 2012. The parties also agree that petitioner started having various non-specific symptoms in mid-April 2011. Petitioner's expert, Dr. Lawrence Steinman, has opined that the onset of her MS was in mid-April 2011. Lay statements from petitioner, [her] mother and boyfriend relate that symptoms could have begun in February or March of 2011.
>
> Respondent's experts (Dr. Richard Tenser and Dr. Harry Schroeder) disagree. The Chief Special Master will need to determine whether petitioner's symptoms beginning in mid-April 2011 was [sic] the onset of her MS, which is the alleged vaccine injury stemming from her human papillomavirus ("HPV") vaccine administered on January 19, 2011.
>
> The issues to be determined … are: (1) when was the onset of petitioner's MS; and (2) has petitioner presented preponderant evidence of a vaccine-related injury based on *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

ECF No. 75. Petitioner filed the CV of Dr. Steinman on January 22, 2018 (Ex. 48, ECF No. 76-1), subsequently filing her pre-hearing submissions, including Petitioner's Pre-Hearing Brief (ECF No. 78)[12] on January 26, 2018.

The docket of this case reflects an informal electronic mail communication remark noted by Chief Special Master Dorsey on January 30, 2018. *See* Informal e-mail communication remark noted on 1/30/2018. That remark indicates that counsel for both parties e-mailed Chief Special Master Dorsey's law clerk informing the Court of their intentions not to submit any additional responsive briefs, and indicating that both parties deem the record of this case to be closed as to further evidence. *Id*.

This case was reassigned to my docket on February 7, 2018. *See* Order of 2/7/2018. This case is now ripe for a decision.

II. FACTUAL BACKGROUND

A. Medical History Appearing in the Medical Records

1. Petitioner's Relevant Medical History prior to her HPV Vaccination of January 16, 2011

Petitioner's pre-vaccination history reflects treatment for depression and a hospitalization for complicated tonsillitis. *See generally* Exs. 23-26.

Petitioner was admitted to the emergency department on January 16, 2011, for psychological evaluation due to her "verbalizing suicidal ideation." Ex. 26 at 1. She gave a history at that time of having "premenstrual dysphoric disorder" that was being treated. *Id*. Upon examination, her primary diagnosis was Depressive Disorder, "NOS" [Not Otherwise Specified], and the follow-up care plan was for Petitioner to be admitted to inpatient psychiatric care. *Id*. at 2.

On January 19, 2011, Petitioner presented to the Mountain Park Health Center for a medication refill and to discuss hypoglycemia. Ex. 2 at 23. She relayed her recent history of going to a "psych hospital," stating that she was kept overnight for feelings of anxiousness and suicidal thoughts. *Id*. Her physical examination was normal, but the remaining notations on that medical record are illegible. *Id*. She received her second dose of the HPV vaccine at that time.[13] Ex. 1 at 1; Ex. 32.

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[12] Petitioner's counsel filed Petitioner's Pre-Hearing Brief (entitled "Petitioner's Opening Brief") into the record of this case two times -- once, as ECF No. 78, and again as ECF No. 79. *Compare* ECF Nos. 78 and 79.

[13] The HPV vaccine is generally administered as either a two-dose, or a three-dose series. *See HPV Vaccine Information for Clinicians* at 4, found at: https://www.cdc.gov/hpv/hcp/need-to-know.pdf (last visited on June 18, 2018). The records reflect that Petitioner received her first HPV vaccination on November 20, 2009. Ex. 25 at 4.

2. Petitioner's Relevant Medical History after her HPV Vaccination: January 16, 2011 through December 2011

On February 24, 2011, Petitioner called her primary care doctor, Rachel Sy, D.O., with complaints of inflamed glands, sore throat, and ear pain, requesting a referral to an Ear Nose and Throat ("ENT") specialist. Ex. 32 at 1.

Petitioner was admitted to Tempe St. Luke's Hospital's emergency room on April 21, 2011, for "generalized weakness." Ex. 3 at 13. The "History of Present Illness" section of that record reflects Petitioner reported that she was feeling weird over the past week (*i.e.*, since April 14, 2011), feeling "light headed and at times confused." *Id*. She reported a history of "hypoglycemia," but relayed that she had not had a formal diagnosis by a physician, additionally stating that she was having symptoms of low grade fevers, chills, and sore throat. *Id*. at 1, 13. Her neurological exam at that time was benign (*id*. at 14), and her laboratory testing -- which included a urinalysis, complete blood count (CBC), and basic metabolic panel (BMP) -- were all within normal limits (*id*. at 13-21). Petitioner's clinical impression was recorded to be "fatigue," and she was discharged with a recommendation to follow up with her primary care doctor. *Id*. at 15-16.

Petitioner followed up with her primary care doctor, Dr. Sy, on April 22, 2011, at which time she was evaluated as having a "distant affect."[14] Ex. 2 at 22. She was seen again by Dr. Sy on April 25, 2011, at which time she provided a recent history of her symptoms, which included neck stiffness, ear and jaw pain, and ear pressure. *Id*. at 21. Dr. Sy additionally noted that Petitioner reported complaints of not being able to drive, not being able to hold a conversation, fogginess of thoughts, numbness, and feeling cold. *Id*.

Petitioner next visited Dr. Sy on May 2, 2011, at which time she reported having bilateral pelvic pain for a "few weeks," and having symptoms of "dizziness," "blacking out," and "throat swelling" for the "past 3-4 wks." Ex. 2 at 20. She additionally relayed a family history of lupus, reporting that her aunt and grandmother suffered from that condition. *Id*. Petitioner again consulted with Dr. Sy on May 4, 2011, reporting that she saw a neurologist who purportedly stated that there was "nothing for him to do," leading her to consult with a hematologist later that month. *Id*. at 19. She reported having the same symptoms as in her recent prior visits, and requested an ENT referral at that time. *Id*.

a. Rheumatology Visits

On May 17, 2011, Petitioner visited a rheumatologist, Stuart Posner, M.D., for further evaluation of "a multiplicity of general medical and constitutional difficulties, chief among which [was] the development of a pattern of fatigue, cognitive disturbance, and polyarthalgic joint pain." Ex. 4 at 7. That record reflects Petitioner's recounting of her recent symptoms and family medical history, and notations of Dr. Posner's impressions of her recent laboratory testing. *Id*. at 7. In this regard, Dr. Posner noted that Petitioner's recent laboratory testing revealed "strongly positive"

[14] This medical record is partly illegible. I additionally note that Dr. Sy's handwritten notations throughout Ex. 2, reflecting her contemporaneous notations of Petitioner's treatment visits, are difficult to read. *See Id*. at 17-23.

ANA [antinuclear antibodies] and a positive rheumatoid factor[15], which "provoked further rheumatologic assessment," especially in light of Petitioner's maternal side of the family having a history of lupus. *Id*. Upon examination, Dr. Posner's clinical impression was that:

> Despite the reported positive rheumatoid factor and ANA, the patient does not exhibit currently pathognomonic or diagnostic features of active inflammatory connective tissue disease, i.e. she does not exhibit alterations on exam of chronic or acute inflammatory synovitis or vasculitis. The possibility that she may be in the process of evolving a connective tissue disease within the spectrum of an autoimmune process such as a lupus or lupus-variant disease cannot be completely excluded however. The issues of other causes for rheumatoid factor and ANA reactivity will have to be further assessed.

Ex. 4 at 7-8. Dr. Posner's plan was to order additional laboratory studies, and to follow up with Petitioner in a few weeks. *Id*. at 8.

Petitioner had a subsequent visit with Dr. Posner on June 9, 2011, to relay the benign findings of a spinal tap examination. Ex. 4 at 6. Additional testing since her last visit revealed that her ESR[16] was elevated, and that she had a positive RF, ANA titer, SS-A and SS-B, and Lyme IgM factors.[17] *Id*. Dr. Posner noted, among other things, that Petitioner "does not exhibit diagnostic features of usual autoimmune disease associated with either lupus or rheumatoid

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[15] Antibodies are immunoglobulin molecules (proteins) with a specific amino acid sequence. Dorland's Illustrated Medical Dictionary (32nd ed. 2012) at 100 (hereinafter "Dorland's"). Antinuclear antibodies (ANA) are a type of antibody directed against nuclear antigens, which are responsible for inducing specific immune responses. *Id.* The immune system makes antibodies to fight infection, while ANAs attack the body's own tissues. *ANA test*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/ana-test/about/pac-20385204 (last visited July 3, 2018). Positive ANA tests indicate that the body has mistakenly attacked its own tissue, with ANA testing often being used to confirm diagnoses of rheumatic diseases. *Id.* Similarly, rheumatoid factors are proteins that the immune system produces that can also mistakenly attack healthy tissues in the body. *Rheumatoid Factors*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/rheumatoid-factor/about/pac-20384800 (last visited July 3, 2018). Positive levels of the factor are most often associated with rheumatoid arthritis and Sjögren's syndrome. *Id.*

[16] Erythrocyte sedimentation rate (ESR) is another blood test that reveals the levels of inflammation in the body. *Sed rate (erythrocyte sedimentation rate)*, MAYO CLINIC, https://www.mayoclinic.org/tests procedures/sed-rate/about/pac-20384797 (last visited July 3, 2018). ESR measures distance of blood cells -- *i.e*., the greater the distance, the greater the inflammatory response. *Id*. Although her ESR was elevated in June 2011, the lab testing from July to December 2011 indicated normal ESR levels. *See* Ex. 5; Ex. 15 at-1 at 18-29.

[17] When testing for ANA is positive (measured in titers), it is appropriate to test the presence of other elevated antibodies common to rheumatic diseases. *SS-A and SS-B Antibodies, IgG, Serum*, MAYO CLINIC: MAYO MEDICAL LABS, https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive /82403 (last visited July 3, 2018). These antibodies can include: RF, SS-A and SS-B (associated with Sjögren's syndrome), and IgM (immunoglobulin M is another infection-fighting antibody). *Id.*

arthritis." *Id*. Dr. Posner outlined a treatment plan for Petitioner to seek an infectious disease consult, and to be on a trial of low dose prednisone[18] for symptom relief. *Id*.

On July 8, 2011, Petitioner had a follow-up with Dr. Posner. At that time, Dr. Posner recorded a summary of Petitioner's recent medical history relating to her care by multiple subspecialists; some of her treating doctors prescribed antibiotics for her suspected Lyme disease, while others suspected a lupus-related disorder. Ex. 4 at 5.

b. Neurology Consults

Petitioner consulted with a neurologist, George Wang, M.D., on June 10, 2011, for complaints of headaches and passing out. Ex. 13 at 29. Petitioner reported that her "headache started about 7 weeks ago." *Id*. She also reported numbness in her extremities, visual disturbance (seeing spots) and "body shaking". *Id.* A neurological examination at that time was unremarkable.[19] Petitioner was assessed as having migraines[20], and was prescribed Fioricet and Topamax.[21] *Id*. at 30-31.

Petitioner continued to see Dr. Wang on several occasions over the next six months. *See* visits with Dr. Wang on: July 1, 2011 (Ex. 13 at 26-28); August 12, 2011 (*id*. at 23-25); and November 22, 2011 (*id*. at 20-22). Notably, on July 1, 2011, Petitioner relayed that she had some new symptoms starting "about 3 weeks ago." *Id*. at 26. She told Dr. Wang that her upper and lower extremities had become weak, and that her weakness was getting to the point that she had trouble getting around. *Id*. at 26-28.

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[18] Prednisone is a synthetic glucocorticoid derived from corticoid, administered as an anti-inflammatory and immunosuppressant. *Dorland's* at 1509. It is often used to treat inflammation and works on the immune system. *Prednisone (Oral route)*, MAYO CLINIC, https://www.mayoclinic.org/drugs-supplements/prednisone-oral-route/description/drg-20075269 (last visited July 3, 2018).

[19] That record also reflects that her cerebral spinal fluid (CSF) testing on May 18, 2011, was normal; and that her laboratory testing on May 17, 2011, revealed positive ANA, and increased ESR. Ex. 13 at 29.

[20] "A migraine can cause severe throbbing pain or a pulsing sensation, usually on just one side of the head.… Aura may occur before or during migraines.… Auras are symptoms of the nervous system. They are usually visual disturbances, such as flashes of light or wavy, zigzag vision. Sometimes auras can also be touching sensations (sensory), movement (motor) or speech (verbal) disturbances. Your muscles may get weak, or you may feel as though someone is touching you.… Examples of migraine aura include: Visual phenomena, such as seeing various shapes, bright spots or flashes of light; vision loss; pins and needles sensations in an arm or leg; weakness or numbness in the face or one side of the body; difficulty speaking; hearing noises or music; and uncontrollable jerking or other movements." *See Migraine, Symptoms and Causes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/migraine-headache/symptoms-causes/syc-20360201 (last visited August 14, 2018).

[21] Fioricet and Topamax are medications commonly used to treat tension and migraine headaches. DRUGS@FDA: FDA APPROVED DRUG PRODUCTS, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm (last accessed on July 3, 2018).

c. Infectious Diseases Specialist

Petitioner consulted with an infectious diseases specialist, Laura K. Schroeder,[22] M.D., on June 15, 2011. At that time, Petitioner reported that she "began experiencing very unusual symptoms in the last few months," including "some brain fog," which progressed into joint pains, in addition to neck and back pain. Ex. 5 at 57. She reported additional symptoms including: ringing in the ears, "some hearing loss in the low ranges," slight numbness of her hands, having loss of motor function, and feeling "uncoordinated at times." *Id*. Dr. Schroeder's treatment plan was that Petitioner had "extremely worrisome symptoms" that comprised "a cluster of unusual neurologic findings, weight loss, staring spells and positive antibody for Lyme disease as well as autoimmune markers." *Id*. at 58.[23] Additionally, Dr. Schroeder noted that "I cannot exclude that Lyme disease alone is responsible for all of this, or whether or not this is a combination of Lyme and lupus." *Id*. Dr. Schroeder's plan was to get further workup and prescribe intravenous Rocephin therapy.[24] *Id*.

On August 12, 2011, Petitioner saw Dr. Schroeder again, at which time she noted that Petitioner was enrolled in online classes due to her disability.[25] Ex. 5 at 51. Dr. Schroeder's impression was that Petitioner continue her ongoing treatment for an autoimmune disorder with prednisone, and treat her Lyme disease with doxycycline (an antibiotic). *Id*. Dr. Schroeder's plan was for Petitioner to continue her dosage of doxycycline for another month. *Id*.

Petitioner was next examined by Dr. Schroeder on December 13, 2011, at which time Petitioner was noted to be "doing well off of doxycycline with no systemic symptoms of [L]yme disease at this time." Ex. 5 at 50. Petitioner was additionally assessed with having a facial skin lesion due to possible impetigo (a common, highly contagious bacterial skin infection), or HSV (herpes simplex virus), and was prescribed Clindamycin (a common antibiotic) for her topical skin lesions.[26] *Id*.

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[22] Dr. Laura K. Schroeder was Petitioner's treating infectious diseases specialist; she has no relationship with Dr. Harry Schroeder, Jr., an immunologist, who proffered an expert opinion on behalf of Respondent in this case.

[23] That record also indicates the results of Petitioner's laboratory testing performed throughout May 2011, with Dr. Posner noting that Petitioner's ESR was 33, and that she was "Sjogren's positive," "rheumatoid factor positive," "ANA titer 1:640," and "Lyme disease IgM" positive. Additionally, her lumbar puncture results were negative for elevated protein or glucose. Ex. 5 at 57.

[24] Rocephin is an antibiotic used for treating or preventing bacterial infections. Rocephin, DRUGS@FDA: FDA APPROVED DRUG PRODUCTS, https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/050585s067lbl.pdf.

[25] Dr. Schroeder wrote a letter for Petitioner's college on July 27, 2011, noting that Petitioner was under her care for a "devastating infection" and "severe autoimmune disease," and requesting that Petitioner be excused from her college classes. Ex. 5 at 53.

[26] Dr. Schroeder's diagnoses at that time are listed as: "Lyme disease"; "Unspecified disorder of skin and subcutaneous tissue"; "skin lesion"; and "systemic lupus erythematosus." Ex. 5 at 50.

d. ENT Specialist

Petitioner saw Timothy Kelsch, M.D., an ENT physician, on July 10, 2011. Ex. 12 at 3-5. The "Assessment & Plan" section of that medical record reflects that Petitioner's sensorineural hearing loss and throat pain had improved from previous visits, and that she was "highly suspected of [having] systemic lupus erythematosus." *Id*. at 5. Dr. Kelsch noted that he was waiting for further recommendations from her rheumatologist prior to assessing Petitioner's treatment plan. *Id*.

e. Laboratory Testing and Diagnostic Imaging

i. MRI Findings

Petitioner underwent a brain magnetic resonance imaging (MRI), without contrast,[27] on April 27, 2011, revealing a "mild cerebellar tonsillar ectopia" that was "suggestive of Chiari I malformation."[28] Ex. 2 at 15-16. The MRI also showed a "mild right mastoid [an area behind the middle ear] air space disease." *Id.*

Petitioner had a brain magnetic resonance angiography (MRA)[29], without contrast, performed on June 16, 2011. Ex. 13 at 13. The results from that testing were unremarkable. *Id*.

Petitioner next had an MRI of the cervical spine, with and without contrast, performed on July 8, 2011, which again revealed unremarkable results -- specifically, no abnormal enhancement of the cervical spine. Ex. 13 at 5-6. On that same date, Petitioner also had a thoracic spine MRI, with and without contrast. Ex. 2 at 31. That MRI revealed subtle hyperintensities from T7-T8

[27] Contrast material is used for MRIs of the brain and spinal cord to enhance the appearance of lesions signifying disease in an active state. MRIs can be performed with injection into the blood of a contrasting agent, such as gadolinium, which serves to increase (or "enhance") the signal of certain types of lesions visible to the radiologist performing the imaging. Active or newer lesions are more likely to enhance than preexisting or older lesions because the contrasting agent is able to enter the brain via an existing breach in the blood-brain barrier; once that barrier is repaired, and the contrast cannot reach the brain, lesions do not appear enhanced. *See W.C. v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 440, 444 (2011).

[28] A Chiari malformation is "a congenital anomaly in which the cerebellum and medulla oblongata, which is elongated and flattened, protrude into the spinal canal through the foramen magnum. It is classified into three types according to severity: *type I* involves prolapse of the cerebellar tonsils into the spinal canal without elongation of the brainstem." Dorland's at 1098.

[29] MRA is a type of MRI that looks specifically at the body's blood vessels. *Magnetic Resonance Angiography*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/healthlibrary/test_procedures/cardiovascular/magnetic_resonance_angiography_135,14 (last visited on July 27, 2018).

compatible with a very small syringohydromyelia;[30] and a small focus of T2 hyperintensity within the inferior T11 vertebral body and may represent more recent development of a Schmorl node[31]. Ex. 2 at 31. Additionally, that MRI revealed that Petitioner had "degenerative changes of the thoracic spine with multilevel minimal disc bulges," but that there was "no significant thoracic spinal canal stenosis." *Id*.

ii. EEG Findings

Petitioner underwent an electroencephalography (EEG)[32] on June 13, 2011, which revealed normal results. Ex. 5 at 18; Ex. 13 at 12.

3. Petitioner's Relevant Medical History from January 2012 through April 2012

On February 6, 2012, Petitioner was examined by Dr. Posner for episodes of rectal bleeding (*see* Ex. 4 at 2); and again on February 13, 2012, for "fatigue and general malaise occurring over a period of three to four days" (*id.*). On her visit of February 13, 2012, Petitioner was diagnosed with "[n]onspecific malaise, possibly due to viral illness with resolution." *Id.*

On February 24 and April 18, 2012, Petitioner visited with her primary care doctor for her bloody stools. Ex. 2 at 17-18. The remainder of the text on that medical record is illegible. *Id*.

Petitioner visited Dr. Wang on March 27, 2012, for complaints of headaches. Ex. 13 at 17-19. Dr. Wang noted that Petitioner has a medical history of lupus, and recorded Petitioner's descriptions of her headaches, which she relayed as causing "tingling and numbness in her extremities with her headache." *Id*. at 17. Upon examination, she was assessed as having "basilar migraine." *Id*. at 19.

Petitioner again visited Dr. Wang for her headaches on April 16, 2012. At that time, she reported that she was "having a new concern with numbness and tingling to the upper and lower extremities," which Dr. Wang deemed as being "consistent with peripheral neuropathy for upper and lower extremities." Ex. 13 at 15. Dr. Wang ordered additional testing to rule out certain

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[30] Syringomyelia is condition in which there is a "development of a fluid-filled cyst (syrinx) within your spinal cord. Over time, the cyst may enlarge, damaging your spinal cord and causing pain, weakness and stiffness, among other symptoms." *Syringomyelia*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/syringomyelia/symptoms-causes/syc-20354771 (last visited on July 25, 2018). Generally, syringomyelia is caused when a condition develops in which brain tissue protrudes into your spinal canal, called Chiari malformation. *Id*.

[31] A Schmorl nodule is a nodule seen in radiographs of the spine, due to prolapse of a nucleus pulposus into an adjoining vertebra. Dorland's at 1283.

[32] An electroencephalogram (EEG) is a test that detects electrical activity in your brain using small, metal discs (electrodes) attached to your scalp. *EEG (electroencephalogram)*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/eeg/about/pac-20393875 (last visited on July 25, 2018). An EEG is one of the main diagnostic tests for epilepsy. *Id*.

disorders, including electromyography (EMG) [33] and nerve conduction studies (NCS) of the upper and lower extremities, and an MRI of the brain. *Id*. Petitioner had her EMG and NCS study done on April 23, 2012, which yielded normal results. *Id*. at 7.

On April 24, 2012, Petitioner presented for her consultation with Dr. Posner as a wheelchair-bound patient. Ex. 4 at 1. Dr. Posner noted that Petitioner "was last evaluated in this office on February 13, 2012 and her clinical condition has changed radically since that visit." *Id*. Upon examination, Dr. Posner noted that Petitioner's exam was "noteworthy for a disassociation between [her] affect being somewhat lighthearted compared to the profound motor difficulty" that she was experiencing at that time, especially in light of the fact that Petitioner was experiencing those symptoms "without obvious localizing neurologic signs." *Id*. Dr. Posner additionally noted that there was still "no clear objective indication of lupus cerebritis or transverse myelitis," and recommended that she follow up with her neurologist. *Id*. Her laboratory testing performed at that time revealed normal results, with positive antibodies for an ANA screen and Sjögren's antibodies ("SS-A" and "SS-B"). [34] *Id*. at 10-12.

Petitioner presented to St. Joseph's Hospital's emergency department on April 25, 2012, and was admitted to the neurology service with complaints of continued worsening of paresthesia and weakness in her bilateral lower extremity ("BLE") for the past month. Ex. 33-1 at 1. At that time, Petitioner reported that she "was in her usual state of health up until 1 year ago when she started developing BLE [bilateral lower extremity] numbness and tingling." *Id*. Additional examinations were ordered to properly assess her care. *Id*. at 3.

On April 26, 2012, Petitioner had an inpatient rheumatology consultation with Gabriel Colceriu, M.D. Ex. 33-1 at 41-43. At that time, Petitioner relayed that approximately one year ago, she "started developing all of a sudden, severe headaches, migraines, brain fogginess, all-over pain and hearing issues." *Id*. at 41. That note also reflects that Petitioner and her family "wonder if there is an association with the Gardasil vaccination that she went through a few months before the development of the symptoms." *Id*. Dr. Colceriu planned for Petitioner to undergo further testing with a plan to tailor Petitioner's treatment depending on those results. *Id*. at 43.

Petitioner underwent an MRI of her cervical spine on April 26, 2012, which her neuroradiologist interpreted as reflecting "[f]indings worrisome for demyelination." Ex. 2 at 9. On that same date, Petitioner also underwent an MRI of her lumbar and thoracic spine, which both revealed unremarkable results. *Id*. at 11-12. She similarly underwent a brain MRI with contrast, the results of which were interpreted by her treating neuroradiologist as being "suspicious for

[33] Electromyography (EMG) studies are conducted when a patient has signs or symptoms indicating a nerve or muscle disorder, such as tingling, numbness, muscle weakness, and certain types of limb pain. *Electromyography (EMG)*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/emg/about/pac-20393913 (last visited on July 4, 2018).

[34] SS-A and SS-B are antibodies associated with Sjögren's syndrome. *See* supra at n. 17. Sjögren's syndrome is an autoimmune disorder which commonly occurs in people with rheumatic diseases, such as rheumatoid arthritis or lupus. *Sjogren's syndrome*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/sjogrens-syndrome/symptoms-causes/syc-20353216 (last visited on July 4, 2018).

demyelination." *Id*. at 13. A multiple sclerosis (MS) panel[35] was performed on April 25, 2012; both the IgG index and the oligoclonal band study were listed as QNS (quantity not sufficient). Ex. 33-1 at 24.

4. Petitioner's Relevant Medical History since April 2012

Since April 2012, Petitioner continued to consult with her primary care doctor, with MS now included in the differential diagnosis. *See* Ex. 8 at 1, 9, 11, 15, 18 (multiple sclerosis listed under "Active Problems," "Past Medical History," or "Assessments" in Petitioner's treatment notes of: August 30, 2012; October 11, 2012; November 19, 2012; January 24, 2013; and March 22, 2013); *see also* Ex. 2 at 1, 3 (treatment note recording a diagnosis of MS on January 8, 2013; and May 2, 2013). She also continued to have abnormal rheumatology findings upon laboratory testing. *See* Ex. 8 at 1, 56-62; Ex. 15-1 at 5-14.

On June 9, 2012, Petitioner underwent brain imaging, which continued to reveal evidence of lesions. Ex. 10 at 2-3. She had an MRI of the cervical spine which revealed resolution of abnormal enhancement at C3-C4 on the right, and otherwise, no significant change in lesions at C2-C3, C3-C4, and C5-C6 when compared to the MRI of April 26, 2012. *Id.* at 4. She also had an MRI of the thoracic spine at that time, reflecting a "small focus of T2 hyperintense signal within the cord at the level of T7-T8" -- results that her neuroradiologist interpreted as "likely represent[ing] a demyelinating lesion" in light of Petitioner's prior medical history and previous thoracic spine imaging. *Id*. at 5-6.

On September 13, 2012, Petitioner saw Kumaraswamy Sivakumar, M.D., at the Neuromuscular Research Center, presenting with weakness in the "distal, proximal, upper extremities, and lower extremities." Ex. 14 at 1. Upon examination, Dr. Sivakumar noted, among other things, that Petitioner's "clinical serological and therapeutic response was consistent with systemic lupus." *Id*. at 3. Dr. Sivakumar additionally noted that, at that time, he considered "multiple sclerosis unlikely given monophasic illness and improving CNS lesions." *Id*. at 3.

Petitioner presented to Barrow NeuroImmunology on October 30, 2012, at which time her treating physician recorded a detailed medical history given by Petitioner. Ex. 9 at 16-20. That history recorded in her medical records, reflects, in relevant part, as follows:

> Her current symptomology began in April 2011, prior to this time she had been relatively healthy except for a few episodes of recurrent peritonsillar abscesses. In February 20[11],[36] she had received a vaccination for Gardasil, despite being HPV positive. In April 2011 she suddenly awoke with a multitude of symptoms, which

[35] An MS – CSF panel measures immunoglobulins (IgG) as well as the number of oligoclonal bands that are present in the CSF. Finding four or more CSF-specific bands is consistent with MS, as is a CSF IgG index of >0.85. *Multiple Sclerosis (MS) Profile*, MAYO CLINIC, MAYO MEDICAL LABS, https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/83305 (last visited July 30, 2018).

[36] That notation is in error regarding the month and year (recorded as "February 2001") in which Petitioner received her HPV vaccine. Ex. 9 at 16.

she brings to us on a list.

Ex. 9 at 16. Petitioner additionally relayed that "she continued to have most of her symptoms but was managing until April of 2012," at which time "she initially noticed tingling in her legs," and "in the course of one week," she was "no longer able to walk." *Id*. at 17. Upon examination, Petitioner's treating physician assessed her as meeting the "2010 McDonalds criteria for clinically definite MS based on clinical history and radiologic progression." *Id*. at 20. Her treating neurologist also noted that Petitioner "likely has a concurrent systemic inflammatory process due to positive serologies and family history[;] however it is not clear to us that she meets diagnostic criteria for SLE or Sj[ö]gren's." *Id*. That record additionally reflected her treating physician's impression of the alleged link between HPV and Petitioner's present condition, stating that "[i]t is unclear of the role of Gardasil in her condition, however, there are case reports/series of Gardasil preceding multifocal and atypical demyelinating syndromes" (*id*. at 20).

Petitioner again visited Barrow NeuroImmunology for further consultations for her MS diagnosis on February 20 and May 3, 2013. On both of those visits, her treating physician noted the unclear role of Petitioner's Gardasil vaccination on her condition, but also made general references to the existence of case reports mentioned during her visit of October 30, 2012. Ex. 9 at 4, 14.

Petitioner continued to seek care for her aggressive form of MS throughout 2013. Her brain imaging reflected findings compatible with demyelinating lesions. *See* Ex. 2 at 1-2; Ex. 18 at 1-8; Ex. 20 at 1-29.

The record additionally reflects a letter written by Petitioner's primary care doctor, Dr. Sy, dated March 5, 2015, in which Dr. Sy states that "[i]n the following weeks" after Petitioner's HPV vaccination of January 19, 2011, Petitioner "began to have symptoms that were initially somewhat vague in nature." Ex. 32 at 1. Furthermore, Dr. Sy states the following in that letter:

> At the time of her [initial] evaluations, I did not think to connect her symptoms to the Gardasil vaccine. However in retrospect it seems very plausible there was a connection to the vaccine. Previous notes by the specialists had indicated her symptoms started in April 2011. However she did have symptoms prior to this time, the symptoms were just more vague in nature and didn't come to our attention until later in the course of the disease. April 2011 was when she presented to the emergency room, not when the symptoms began. As evidenced by her call requesting ENT evaluation, she had at least some symptoms in February, 2011.[37] An admission note from St. Joseph's hospital in 4/25/12[38] documents her symptoms as starting 2 weeks after the Gardasil vaccine was given.

[37] Dr. Sy notes that, in February 2011, Petitioner complained of inflammed glands, sore throat, and ear pain. *See* Ex. 32 at 1.

[38] Dr. Sy makes a vague reference to the records from Petitioner's treatment at St. Joseph's Hospital's emergency department on April 25, 2012 (*see* Ex. 33-1), but does not give a specific citation to the exact record she is referring to. *See* Ex. 32 at 1. Dr. Sy was mistaken in her statements in that letter, however, as her statements were based on an incomplete examination of the entirety of Petitioner's medical records

Ex. 32 at 1.

B. Additional Factual Allegations Made in Support of Petitioner's Claim

1. Affidavit of Petitioner

Petitioner signed an affidavit on November 5, 2014. *See* Ex. 27 at 2. Petitioner first described herself prior to the HPV vaccination of January 19, 2011, averring that she was a student in the honors college at Arizona State University studying Civil Engineering. *Id.* at 1, ¶¶ 3-4. She lived a very physically active lifestyle, which included playing sports and riding her bike around Tempe, Arizona. *Id.*, ¶5.

Petitioner next described her state of health after her HPV vaccination of January 19, 2011. Specifically, she averred that in early February 2011, she began to feel "very sleepy," "generally weak all over," felt "constantly tired," and had "body pain." Ex. 27 at 1, ¶7. She stated that her feelings of weakness and discomfort got worse over time, and that her family "knew something was really wrong with me" when she visited her family over college spring break. *Id.*, ¶8. She additionally stated that by March 2011, she was "no longer participating in [her] normal activities and was having a hard time physically doing daily activities." *Id.*, ¶9. Notably, she alleged that she had "early signs of issues with walking" prior to April 2011 (*id.*, ¶10), but that she did not realize the connection until those symptoms worsened in April 2011, at which time she had "all over pain and paralysis" (*id.*, ¶11).

2. Affidavit of Caylee Harrington in Case Number 14-212V

Petitioner also submitted an affidavit in case number 14-212V, as discussed *supra* at Section I(A), signing that affidavit on March 13, 2014. Ex. A at 2. Respondent filed that affidavit into the record, as certain of Petitioner's allegations in that affidavit are at variance with her

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since her admission to the emergency room on April 25, 2012. For one, Petitioner's emergency department records of April 25, 2012 reflect that Petitioner reported she "was in her usual state of health up until 1 year ago when she started developing BLE [bilateral lower extremity] numbness and tingling." Ex. 33-1 at 1. That is, according to the history provided by Petitioner to her emergency department physician on April 25, 2012, she placed the onset of her symptoms *around April of 2011*. *Id.* Second, while that record does reflect that Petitioner relayed to her emergency department physician that her symptoms were "preceded by getting a Gardasil shot 2 weeks prior" (*id.* at 1), that statement is further explained by what she relayed just *one day later* to another doctor during her inpatient stay, Dr. Gabriel Colceriu, on April 26, 2012 (*id.* at 41-43). During her consultation with Dr. Colceriu on April 26, 2012, Petitioner once again relayed that she started experiencing symptoms "[a]bout a year ago," but that she and her family "wonder if there is an association with the Gardasil vaccination that she went through a few months before the development of the symptoms." *Id.* at 41. In other words, Petitioner and her family relayed to another physician on April 26, 2012, their suspicions that Petitioner's Gardasil vaccine administered "a few months before the development" of her symptoms could possibly be related to her then-current condition on April 26, 2012. *Id.* I also point out that, despite Petitioner relaying her suspicions of a vaccine-related cause of her symptoms to Dr. Colceriu, he did *not* attribute her symptoms to her Gardasil vaccination, despite noting that "[e]xtensive records from the outpatient setting were reviewed" at that time. *Id.* at 43.

statements in this case. Notably, in that affidavit, Petitioner averred that she felt healthy until the middle of March 2011, at which time her post-HPV vaccination symptoms began. Ex. A at 1, ¶ 5. Petitioner also stated as follows:

> After the middle of March, 2011, I began to experience (in addition to other symptoms) intermittent bilateral upper extremity, intermittent facial numbness, bilateral lower extremity numbness and tingling; neck and back pain, pressure in the ears, dizziness, brain fog, confusion, decreased memory and muscle weakness.

Ex. A at 1-2, ¶7.

3. Affidavit of Catherine Harrington ("Ms. Harrington")

Petitioner's mother, Catherine Harrington, signed an affidavit on November 5, 2014. *See* Ex. 28 at 2. Ms. Harrington stated that she spoke to her daughter "almost daily" (*id*. at 1, ¶5), and described her state prior to the HPV vaccination of January 19, 2011, as one in which she led a very active lifestyle enjoying racquetball, horseback riding, and bike riding (*id*., ¶4).

Ms. Harrington also described Petitioner's state after her HPV vaccination of January 19, 2011. She asserted that Petitioner began to complain of her symptoms in February 2011, describing Petitioner as feeling weak in most of their conversations, with her weakness gradually progressing until her spring break in March 2011, at which time she complained of "fatigue and an over-all ill feeling." Ex. 28 at 1, ¶ 6. Moreover, Ms. Harrington asserted that, by March 2011, "Petitioner was no longer able to participate in her normal activities" (*id.*, ¶7). She stated Petitioner's symptoms included "lethargy," "cognitive dysfunction," difficulty walking, and "severe migraines" (*id.*, ¶10).

Ms. Harrington relayed that she originally thought that Petitioner's symptoms were due to her "being over extended," as she was a full-time student and working part-time. She also thought her symptoms were due to Petitioner's depression. Ex. 28 at 1, ¶8. Moreover, Ms. Harrington stated that Petitioner's symptoms progressed to her eventual emergency room visit in April 2011 (*id.*, ¶11), at which time her symptoms had "progressed to transient paralysis and over all pain" (*id.*, ¶12). She additionally relayed that Petitioner continues to experience these symptoms periodically and with varying intensity. *Id.* at 2, ¶13.

4. Affidavit of Michael Collier

Mr. Collier signed an affidavit on November 5, 2014. *See* Ex. 29 at 2. He has known Petitioner since early 2010 when they began dating; they eventually moved in together in May 2010. *Id.* at 1, ¶¶3, 6. Mr. Collier averred to Petitioner's state of health prior to her HPV vaccination of January 19, 2011, asserting that she led an active lifestyle, which included rock climbing, shooting, fishing, hiking, and cooking, among other activities. *Id.*, ¶¶6-9.

Mr. Collier additionally described Petitioner's state after her HPV vaccination of January 19, 2011. He asserted that as of February 2011, he noticed that "Petitioner was not the same" as she was "feeling very tired and weak" (Ex. 29 at 1, ¶11), with additional symptoms of

lightheadedness, neck stiffness, and soreness (*id.*, ¶12). Mr. Collier stated that her symptoms continued to progress to the point that she was unable to hold a conversation, causing her friends to encourage her to consult a doctor. *Id.*, ¶12. He additionally stated that, by mid-March 2011, "it was clear to me that something significant was really wrong with her." *Id.* at 2, ¶13. Those symptoms worsened over time, eventually causing Petitioner to use a wheelchair while at home (*id.*, ¶14).

5. Affidavit of Treating Nurse Practitioner, Teresa Becker, FNP

Ms. Becker signed an affidavit on December 11, 2014. *See* Ex. 30 at 2. Ms. Becker averred to being a treatment care provider for Petitioner prior to 2008, at which time she was operating a private practice. She represented that Petitioner's medical records were shredded at the closing of her practice. *Id.* at 1, ¶¶ 3, 6. Ms. Becker stated that she mainly provided routine health care to Petitioner prior to 2008 (*id.*, ¶7), observing that she was a "physically healthy young girl" (*id.*, ¶10), who received counseling by another treatment provider for her depression (*id.*, ¶8).

6. Affidavit of Treating Licensed Professional Counselor, Julie Nicholson

Ms. Nicholson signed an affidavit on December 18, 2014. *See* Ex. 31 at 2. Ms. Nicholson averred to briefly being a treatment care provider for Petitioner in either 2004 or 2005, while operating a private practice; she also stated, however, that Petitioner's medical records were shredded at the closing of her practice. *Id.* at 1, ¶¶ 4-5. Ms. Nicholson stated that she only briefly provided treatment to Petitioner for her situational depression, that Petitioner eventually overcame her situational depression; she described Petitioner as an otherwise healthy young girl. *Id.* at 1-2, ¶¶ 6, 9.

III. ISSUES TO BE DETERMINED

The issues to be determined are: (1) what was the date of onset for Petitioner's MS; and (2) did Petitioner's receipt of a HPV vaccine on January 19, 2011, cause her MS.

IV. SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, each side relies upon the reports of medical experts. Lawrence Steinman, M.D., provided an opinion on behalf of Petitioner, while (1) Richard Tenser, M.D., and (2) Harry Schroeder, M.D., Ph.D., provided an opinion on behalf of Respondent.

A. Petitioner's Expert – Lawrence Steinman, M.D.

1. Qualifications

Dr. Steinman received his medical degree from Harvard University in 1973. Ex. 48 at 1. Dr. Steinman completed his residency training in pediatric and adult neurology at Stanford University Hospital. *Id.* He became board-certified in neurology from the American Board of Psychiatry and Neurology in 1984. *Id.* at 2.

Dr. Steinman started as an Assistant Professor at Stanford University in the Departments of Neurology and Pediatrics in 1980, and has held the position of Professor since 1991. Ex. 48 at 1. From 2002 to 2011, he served as Chairman of Stanford University's Program in Immunology, and as Incumbent Zimmermann Chair of Neurological Sciences, Neurology, and Pediatrics, from 2008 to present. *Id.* Dr. Steinman holds numerous patents relating to the treatment of MS and other autoimmune disorders, has served as an editor for several prestigious journals, and has co-authored more than five hundred publications throughout his career. *Id.* at 1-46. In 2011, Dr. Steinman received the Charcot Prize from the International Federation of MS Societies for lifetime achievement in MS research. Ex. 35 at 2.

2. Medical Opinion

a. Onset

Dr. Steinman briefly opines as to the onset of Petitioner's MS symptoms, stating that the onset of "*clinical* MS began no earlier than mid-April 2011." Ex. 35 at 1, emphasis in original; *see also id.* at 3 ("the onset of clinical symptoms of MS, began sometime in April of 2011.") He specifically points to Petitioner's emergency room admission on April 21, 2011, citing to her complaints of "general weakness" as the start of her MS symptoms. *Id.* at 3. Dr. Steinman also points to Petitioner's subsequent complaints recorded in the medical records for various non-specific symptoms, such as: "distant affect" (citing primary care doctor's impression on April 22, 2011), and "malaise and fatigue" (citing her MRI of April 27, 2011). *Id.*, internal citations omitted. He discounts the unremarkable results of Petitioner's MRI conducted on April 27, 2011, revealing no evidence of MS, as not being probative regarding her MS onset because "contrast was not given" at that time. *Id.* at 3.

While Dr. Steinman acknowledges that Petitioner's medical records reflect that her treating physicians believed she concurrently suffered from "other connective tissue diseases," including Lupus and Sjögren's syndrome, he did not articulate how symptoms from those disorders could be differentiated from Petitioner's purported onset of MS symptoms starting in mid-April 2011. *See* Ex. 35 at 32.

b. Did the Receipt of the HPV Vaccination on January 19, 2011 Trigger Petitioner's MS?

i. General Causation (Althen Prong One)

Dr. Steinman devotes a substantial majority of his first expert report to explaining the theoretical underpinning of his general causation opinion in this case -- *i.e.*, how the HPV vaccination can lead to an autoimmune disorder such as MS, via the mechanism of molecular

mimicry.[39] *See* Ex. 35 at 4-31. The crux of Dr. Steinman's molecular mimicry theory can be summarized as follows: (1) as shown in certain foundational literature, the human papillomavirus shares certain molecular similarities with myelin basic protein (MBP)[40] -- a protein critical for the proper functioning of the nervous system; (2) under experimental conditions, when injected with the human papillomavirus, cells of the nervous system formulate "antibodies to HPV" (*i.e.*, proteins naturally produced by the immune system to neutralize the threat from the human papillomavirus) causing cross-reactivity with the myelin basic protein; (3) this cross-reaction phenomenon between HPV antibodies and myelin basic protein can reach a certain threshold, at which time an immune reaction induces causing "clinical neuroinflammation and paralysis in the EAE [Experimental Autoimmune Encephalomyelitis] model of MS"[41] -- an experimental mice model widely used in MS drug research[42]; and (4) this theoretical concept of "molecular mimicry," as demonstrated in an EAE mice model, can be analogized to the human body, and, according to Dr. Steinman, can serve as a "*strong scientific basis for how the HPV vaccination can trigger MS*" in humans. Ex. 35 at 26, emphasis in the original.

In his first expert report, Dr. Steinman systematically discusses the literature underlying the theoretical basis to support the viability of his general causation theory. *See generally* Ex. 35. He first describes the basic tenets of molecular mimicry[43] (*see* Ex. 35 at 4), followed by a detailed discussion of the specific literature that he co-authored ("the Wucherpfenning article"),[44] in which

[39] I note that, on a theoretical basis, the basic biologic process of molecular mimicry has been "largely accepted in the medical community." *Taylor v. Sec'y of Health & Human Servs.*, No. 13-700V, 2018 WL 2050857, at *8 (Fed. Cl. Spec. Mstr. Mar. 9, 2018). Moreover, the basic tenets of the molecular mimicry theory have been cogently discussed in several recent Vaccine Act cases in which petitioners allege autoimmune disorders caused by the Gardasil vaccination. *See Giannetta v. Sec'y of Health & Human Servs.*, No. 13-215V, 2017 WL 4249946 (Fed. Cl. Spec. Mstr. Sept. 1, 2017); *Day v. Sec'y of Health & Human Servs.*, No. 12-630V, 2015 WL 8028393 (Fed. Cl. Spec. Mstr. Nov. 13, 2015); *Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935 (Fed. Cl. Jan. 9, 2015); and *Salmins v. Sec'y of Health & Human Servs.*, No. 11-140V, 2014 WL 1569478 (Fed. Cl. Spec. Mstr. Mar. 31, 2014).

[40] *See* Wucherpfennig et al., *Recognition of the immunodominant myelin basic protein peptide by autoantibodies and HLADR2-restricted T Cell Clones from multiple sclerosis patients: Identity of key contact residues in the B-cell and T-cell epitopes*, Journal of Clinical Investigation, 100:1114-1122 (1997).

[41] Gautam et al., *A viral peptide with limited homology to a self-peptide can induce clinical signs of experimental autoimmune encephalomyelitis*, Journal of Immunology, 161:60-64 (1998); *see also* Gautam et al., *Minimum structural requirements for peptide presentation by major histocompatibility complex class II molecules: Implications in induction of autoimmunity*, Proceedings of the National Academy of Sciences USA, 91:767-771 (1994).

[42] Rudick et al., *Natalizumab: Bench to bedside and beyond*, JAMA Neurol 70(2):172–182 (2013); Steinman et al, *From defining antigens to new therapies in multiple sclerosis: Honoring the contributions of Ruth Arnon and Michael Sela*., J Autoimmun. 54:1-7 (2014); Steinman et al., *Development of therapies for autoimmune disease at Stanford: a tale of multiple shots and one goal*. Immunol Res. 58(2-3):307-14.

[43] Steinman L, *Autoimmune Disease*, Scientific American Vol. 269: 106-114 (1993).

[44] *See* Wucherpfennig et al., *supra* at n. 40.

it was shown that the human papillomavirus shares molecular similarities with myelin basic protein within a specific region of that protein (*id*. at 5). Moreover, Dr. Steinman elaborates on the Wucherpfenning article, explaining that, in that study, he and his co-authors "showed that antibodies to myelin basic protein eluted from the brain of a patient with multiple sclerosis crossreact with papillomavirus." *Id*. at 6. He uses that finding from the Wucherpfenning article to analogize and extrapolate how a similar phenomenon can occur in humans given the HPV vaccination, thus inducing inflammation of the nervous system, leading to demyelinating conditions such as MS. *Id*.[45]

Dr. Steinman next discusses the HPV vaccine. He describes the composition of the HPV vaccine -- or the "Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18)" vaccine (Ex. 35 at 6) -- as being a "non-infectious recombinant quadrivalent vaccine prepared from the purified virus-like particles (VLPs) of the major capsid (L1) protein of HPV Types 6, 11, 16, and 18" (*id*.). In this regard, Dr. Steinman concedes that the specific components of the Gardasil vaccine were not tested in the Wucherpfenning article. *Id*. at 8.[46] Rather, he analogizes from that article to explain how a specific critical antibody binding site, derived from one of the human brain tissue samples studied in the Wucherpfenning article -- "the FK residue" -- is commonly shared "between the L2 proteins of [the human papillomavirus studied in the Wucherpfenning article], the L1 protein of HPV used to make Gardasil…and myelin basic protein." *Id*. at 11. Through such an inference, Dr. Steinman concludes that the concept of molecular mimicry explains "how immunization with Gardasil containing the L1 protein can lead to antibodies that cross react with myelin basic proteins." *Id*.

Dr. Steinman additionally explains that similar types of homology as the one described above, between the Gardasil vaccine and myelin basic protein, can be strengthened with substitutions of amino acids at relevant binding sites. *See* Ex. 35 at 11-12 (Dr. Steinman's explanation regarding these substitutions includes his reliance upon the Hausmann[47] and Birnbaum[48] articles). He further explains that when a certain threshold of homology is reached between (1) a virus (such as the Gardasil vaccine) and (2) myelin basic proteins (such as those studied in the tissue samples of mice), an autoimmune condition called "experimental autoimmune encephalomyelitis" is induced in mice under laboratory conditions. Ex. 35 at 12-14; *see also* the

[45] Ex. 35 at 6 ("An immunization to HPV could thus induce a cross-reaction with antibodies and T cells that react to myelin basic protein, and could thus trigger brain inflammation.").

[46] *See* Ex. 35 at 8 ("The study with Wucherpfennig and colleagues … shows how antibodies to HPV types 7, 13, 40 and 32 can cross-react with … myelin basic protein. The cross-reaction to the components of Gardasil subtypes 6, 11, 16, and 18 [were] not tested in [the Wucherpfenning article]."); *see also* Wucherpfennig et al., *supra* at n. 40.

[47] Hausmann et al., *Structural features of autoreactive TCR that determine the degree of degeneracy in peptide recognition*, J Immunol. 162(1):338-44 (1999).

[48] Birnbaum et al., *Deconstructing the Peptide-MHC Specificity of T Cell Recognition*, Cell 157(5):1073-87. doi: 10.1016/j.cell.2014.03.047 (2014).

"Gautam 1998"[49] and "Gautam 1994"[50] articles. Dr. Steinman concedes that the mice model studied in the literature relates to a specific type of immune response that is triggered in a *different clinical disease* -- Acute Disseminated Encephalomyelitis (ADEM) -- but submits that ADEM can be characterized as being "an MS like disease."[51] Ex. 35 at 14.

Moreover, Dr. Steinman discusses the relevant literature that followed the studies noted above, deeming those studies to provide additional support towards establishing the theoretical viability of his molecular mimicry theory leading to autoimmunity with the HPV vaccine. *See* Ex. 35 at 19-26 (Dr. Steinman's discussion of several studies, including the Birnbaum,[52] Harkiolaki,[53] and Hausmann[54] articles). He additionally opines that the alum[55] contained in the Gardasil vaccine serves to provide a "more vigorous immune response" to this entire molecular mimicry phenomenon that he opines occurred in this case. Ex. 35 at 26. In other words, he believes that the alum contained in the Gardasil vaccine strengthens the molecular mimicry mechanism in humans to induce cross-reactivity between components of the Gardasil vaccine and myelin basic protein.

Dr. Steinman discounts the epidemiological study that was submitted by Respondent -- the Scheller study[56] -- as not being persuasive in disproving a general association between the HPV vaccine and clinical MS. In this regard, Dr. Steinman points out what he deems are "vast limitations" of the Scheller study, highlighting flaws that the authors of that study articulated, and

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[49] Gautam et al., *A viral peptide with limited homology to a self-peptide can induce clinical signs of experimental autoimmune encephalomyelitis*, Journal of Immunology, 161:60-64 (1998).

[50] Gautam et al., *Minimum structural requirements for peptide presentation by major histocompatibility complex class II molecules: Implications in induction of autoimmunity*, Proceedings of the National Academy of Sciences USA, 91:767-771 (1994).

[51] *See* Ex. 35 at 14 (reflecting Dr. Steinman's discussion analogizing ADEM studied in a mice model and his relevant inferences to MS: "In the mouse we were attempting to elicit ADEM, an MS like disease. So here I use as a cornerstone of my theory these experiments to demonstrate how the Gardasil vaccine can induce an immune response to myelin basic protein, leading to multiple sclerosis. The EAE model was critical for the development of 3 drugs for MS, one of which came from my lab.").

[52] Birnbaum et al., *Deconstructing the Peptide-MHC Specificity of T Cell Recognition*, Cell 157(5): 1073-87 (2014).

[53] Harkiolaki et al., *T cell-mediated autoimmune disease due to low-affinity crossreactivity to common microbial peptides*, Immunity 30(3):348-57 (2009).

[54] Hausmann et al., Structural features of autoreactive TCR that determine the degree of degeneracy in peptide recognition, J Immunol. 162(1):338-44 (1999).

[55] *See* Ex. 35 at 26 ("Gardasil contains alum").

[56] *See* Ex. B, Scheller et al., *supra* at n. 9; *see also* Ex. 37 at 11-18, ECF No. 43-3 (reflecting the same Scheller et al. article submitted by Petitioner in conjunction with Dr. Steinman's first expert report).

the shortcomings of other similar studies.[57] *See* Ex. 35 at 27-29. Dr. Steinman summarizes what he perceives to be the limitations of the Scheller study, and the limitations of the additional epidemiologic studies discussed in that article, by stating that "there is no valid study on a *US population* that can establish that HPV vaccine does not associate with an increased incidence of MS." Ex. 35 at 29, emphasis added. In other words, he heavily discounts those articles for not studying a US population, which he believes is not a good demographic proxy for the non-US population studies in those articles.

ii. Specific Causation (Althen Prong Two)

Dr. Steinman provides a cursory discussion as to his specific causation opinion in this case -- *i.e.*, whether the HPV vaccination received by Petitioner on January 19, 2011 *did* cause her MS. While Dr. Steinman states the conclusion that Petitioner's "immunization on January 19, 2011 triggered a series of immune responses to myelin that induced neuroinflammation in [her] brain" (Ex. 35 at 32), he provides little analysis as to *why* that might be so in this case. Dr. Steinman simply states that he conducted an analysis of the Gardasil package insert to reach his specific causation opinion, but fails to provide any further elaboration of what exactly the analysis was that he conducted while examining the contents of that package. *Id*.

The support from Petitioner's medical records that Dr. Steinman does provide for his conclusion initially appears to be compelling. Upon closer examination of that referenced medical record, however, it does *not* provide significant support for his conclusion. In Dr. Steinman's First Expert Report, he states that "[Petitioner]'s treating neurologists mentioned [at Ex. 9 at 14] that Gardasil and MS had been discussed in the literature." *See generally* Ex. 35 at 4. The actual reference in that medical record reflects the following:

> [T]here is an unclear role of Gardasil vaccinations in her condition; however there are case reports/series of Gardasil preceding multifocal and atypical demyelinating syndromes, which the pt [patient] experienced and is documented in a previous visit.

Ex. 9 at 14. Thus, while treating neurologists from Barrow NeuroImmunology did make general references to the existence of "case reports/series of Gardasil preceding multifocal and atypical demyelinating syndromes," those treating neurologists specifically noted their assessments of the unclear role of Petitioner's receipt of the Gardasil vaccination on her condition. *Id*. In short, the citation to the medical records that Dr. Steinman uses to provide support for his specific causation opinion in this case merely supports an unclear role that the Gardasil vaccination played in Petitioner's development of MS. When examining Ex. 9 at 14 (Petitioner's Barrow NeuroImmunology treatment visit of February 20, 2013) in the context of Petitioner's other treatment visits to that medical practice, the record reflects that Petitioner presented to Barrow NeuroImmunology on several occasions: on October 30, 2012 (*see* Ex. 9 at 16-20); on February 20, 2013 (*id*. at 11-15); on March 22, 2013 (*id*. at 6-10); and on May 3, 2013 (*id*. at 1-5). In aggregate, those visits to several different neurologists within that same medical practice reflect that the neurologists consistently noted an assessment of an unclear role of the Gardasil vaccination

[57] Dr. Steinman copies and pastes the relevant excerpts from the Scheller study in which the authors articulate their study's limitations. *Compare* Ex. 35 at 27-29, with Ex. B at 5-7.

on Petitioner's condition. *See* Ex. 9 at 4, 14, 20.

I additionally note that while Dr. Steinman cites to a particular medical record in which the treating neurologists from Barrow NeuroImmunology made references to case series/reports regarding the Gardasil vaccine preceding demyelinating conditions in general, Dr. Steinman fails to submit or discuss any such literature in support of his position. *See generally* Ex. 35 at 4. Dr. Steinman's mere references to literature, without actually providing that literature, and his failing to provide any additional explanations as to what that purported literature represents, add little weight towards Petitioner's burden of demonstrating specific causation in this case.

iii. Temporal Association (Althen Prong Three)

1. Timing Opinion Provided in First Expert Report

Dr. Steinman opines that the timing between Petitioner's HPV vaccination of January 19, 2011, and the onset of Petitioner's MS -- which, according to Dr. Steinman, occurred sometime in mid-April 2011 -- is medically appropriate in this case. Ex. 35 at 1, 32.

At the outset, I note that the majority of Dr. Steinman's discussion that forms the basis of his opinion on timing is of limited persuasive value, and serves to confound the issues when his explanations veer into discussions of questionable relevance.[58] For instance, Dr. Steinman discusses an epidemiology study in his first expert report -- the Ahmed study[59] -- which examined a *different vaccine* (the Pandemrix vaccine) and a *different disease* (narcolepsy). Ex. 35 at 29. He discusses the results of the Ahmed study, highlighting that the "onset of [narcolepsy] associated

[58] *E.g.*, Ex. 35 at 1 (reflecting Dr. Steinman's attempt to redefine the meaning of "onset" in MS patients to argue a theory of significant aggravation: "I shall also comment on the matter of what we mean by "onset of multiple sclerosis". Since there are over 100 genes associated with MS, indeed the onset of MS, might begin before birth and the 'onset' may be in the genome of the MS patient."); *see also Id*. ("Matters like whether immunization triggers MS, might then be considered an aggravation of an underlying genetic predisposition"); *Id*. at 31 ("Finally it is well to remember that with over 100 genes associated with MS, it is difficult to know when MS commences. MS may start at conception from having genes conferring susceptibility to disease. This perspective with our understanding of the role of genes in susceptibility to MS, makes Althen prong three a real challenge to address.") I note, however, that significant aggravation is *not* at issue in this case since Dr. Steinman did not elaborate on such a theory after his cursory remarks noted above. *See generally* Dr. Steinman's first through sixth expert reports.

[59] Ahmed et al., *Antibodies to influenza nucleoprotein cross-react with human hypocretin receptor 2*, Sci. Transl. Med. 7, 294ra105 (2015).

with [the Pandemrix vaccine] far exceeded three months." *Id*.[60] Dr. Steinman attempts to analogize the results of that study as support for his temporal opinion in this case -- *i.e.*, that Petitioner's onset of MS symptoms can occur in a three-month time frame after her HPV vaccination. *Id.* Dr. Steinman does not explain how the epidemiology results from a different vaccine and a different disease are at all relevant to establish the appropriate temporal association in this case.[61]

In a similar fashion, Dr. Steinman submits additional case reports and epidemiological findings involving the flu vaccine and narcolepsy from several European countries, but again fails to provide a cogent explanation as to how or why any of those studies can be analogized to the incidence of MS occurring approximately three months after HPV vaccination. Ex. 35 at 30-31. In fact, at the end of his lengthy discussion of the literature examining the flu vaccine and narcolepsy, Dr. Steinman himself implicitly acknowledges his own lack of conviction in the relevancy of those articles. *See* Ex. 35 at 31, emphasis added ("Whether the epidemiology of narcolepsy associated with influenza vaccine serves as a surrogate for the time course of another disease, multiple sclerosis, with another vaccine HPV, is a point that can be debated in court if necessary").

Dr. Steinman does reference literature that is counter to his proposed timing in this case -- the Sutton study[62] -- which described "four patients who developed MS following HPV immunization" in Australia. Ex. 35 at 31. Dr. Steinman concedes that none of those four patients had an onset of MS symptoms at three months, but discounts the results of that study due to the small sample size, describing that study as "not easily speak[ing] for what might be the case in the US." *Id*.

In sum, Dr. Steinman's opinion on this issue lacks the foundational basis to explain how the HPV vaccination can trigger Petitioner's onset of MS three months after her vaccination.

2. Timing Opinion Explained in Second and Third Expert Reports

Dr. Steinman devotes his second and third expert reports to providing a foundation for his timing opinion in this case. *See generally* Exs. 40 and 42. In those reports, he primarily discusses

[60] I additionally point out that by Dr. Steinman discussing the Ahmed study, and using that study to serve as a basis to substantiate his timing opinion in this case, he *contradicts his own earlier criticisms* of the Scheller study (Ex. B), as the Ahmed study *also* relies on a *non-US population sample* for their study. *Compare* Ex. 35 at 29 (Dr. Steinman criticizing the Scheller study by stating that "there is no valid study on a US population that can establish that HPV vaccine does not associate with an increased incidence of MS"), with Ex. 35 at 29-30 (Dr. Steinman discussing epidemiology findings conducted in non-US populations that studied the Pandemrix vaccination and narcolepsy to extrapolate those findings to support his temporality opinion in this case).

[61] I note that discussion and analysis of a vaccine that purportedly causes a different demyelinating disease may be of greater persuasive value; narcolepsy is not such a disease.

[62] Sutton, *CNS Demyelination and HPV Vaccine,* Multiple Sclerosis 15: 116-119 (2009).

the "Langer-Gould" article[63] that he states provides a "very solid foundation" for his position. Ex. 40 at 1. He references Figure 1B of that article (*see* Ex. 41 at 64-65), and the authors' interpretations of their results (*id*. at 62), providing the following relevant text from that article:

> In the 3 years prior to symptom onset (or the index date), HPV vaccination was common among females aged 9 to 26 years (controls, 38.1%; and cases, 39.1%) (Figure 1B), but the number of cases in this subgroup was small (n = 92). Based on these few cases and the 459 corresponding controls, we observed a statistically nonsignificant trend toward an increased risk of MS but not CIS or ADEM within the first 3 months after HPV vaccination (Figure 1B). The number of vaccinated individuals 30 days before symptom onset or before the index date for the controls was too low to draw any conclusions (Figure 1B).

Ex. 40 at 2, quoting Ex. 41 at 62. Dr. Steinman argues that the discussion regarding a "statistically nonsignificant trend toward an increased risk of MS…within the first 3 months after HPV vaccination" described above meets his burden to "satisfy the criterion of the preponderance of evidence" on this issue. Ex. 40 at 2.

I note that Dr. Steinman's discussion on the Langer-Gould article is unpersuasive. He initially overstates the strength of that article as supportive of his position, stating that the article provides a "very solid foundation" for his timing opinion. Ex. 40 at 1. Instead of further explaining why that article provides a strong foundation for his opinion, Dr. Steinman's subsequent discussion veers into his own legal opinion as to the appropriate standard in Vaccine Act cases (*see* Ex. 40 at 2-3) -- a discussion I find to be unpersuasive.

Additionally, while Dr. Steinman selects results that support his proposition from the Langer-Gould article, he ignores the *overall finding* of that study, that the authors found "no increased risk of CNS ADS [central nervous system demyelinating syndromes] 30 days after vaccination" -- a finding which the authors themselves interpreted as "arguing against causality" of vaccines triggering MS, or any other central nervous system demyelinating syndromes. Ex. 41 at 66. When asked to clarify his opinion regarding this inconsistency, Dr. Steinman's third expert report points out what he perceives as major flaws in that study,[64] thus undercutting his own cited literature.

B. Respondent's Experts

1. Richard Tenser, M.D.

[63] Langer-Gould et al., *Vaccines and the risk of multiple sclerosis and other central nervous system demyelinating diseases*, JAMA Neural. 71:1506-1513 (2014). That article is reflected on Ex. 41 at 60-67, ECF No. 45-2.

[64] *E.g.*, Ex. 42 at 3 ("I think that Langer-Gould and colleagues' conclusion makes no immunologic sense at all."); *Id.* ("I am very surprised that Langer-Gould and colleagues are deviating from two of the cornerstones of published work on the relationship between vaccination and neurologic disease.").

a. Qualifications

Dr. Tenser received his medical degree from State University of New York (SUNY) Upstate Medical School in 1968. Ex. D at 1. Dr. Tenser completed his residency training in neurology at Yale University School of Medicine, serving as Chief Resident during his final year. *Id*. He became board-certified in neurology from the American Board of Psychiatry and Neurology in 1974. *Id*. at 2.

Dr. Tenser started as an Assistant Professor at The Pennsylvania State University College of Medicine in the Departments of Medicine (Neurology) and Microbiology in 1976, and has been a full Professor at the university since 1986. Ex. D at 1. He has served as a scientific reviewer for several renowned scientific journals, and has been a member of several prestigious professional medical societies. *Id*. at 2-4. He states that he has published over one hundred articles in the areas of virology and MS. Ex. C at 1. Dr. Tenser also cares for a large MS patient population in his clinical practice, personally following more than 500 MS patients. Ex. C at 1.

b. Medical Opinion

i. Onset

Dr. Tenser opines that Petitioner was correctly diagnosed with MS in April 2012, pointing to the medical records from that time reflecting "myelitis, with abnormal brain and spinal cord MRI studies." Ex. C at 3. Dr. Tenser refutes the statements made by Petitioner's primary care doctor, Dr. Sy, in a letter dated March 6, 2015 (*see* Ex. 32), in which she retrospectively commented on the onset of Petitioner's symptoms. Dr. Tenser addresses Dr. Sy's opinion on onset by pointing to Petitioner's emergency room visit on April 21, 2011 (*see* Ex. 3 at 13), noting that her symptoms reflected at that time were "nonspecific as far as MS is concerned." Ex. C at 3. He explains that the neurological exam conducted in April 2011 did not reveal a history of "loss of vision or diplopia, focal weakness/sensory loss" (*id*.), and did not reflect abnormalities in motor functions, coordination, and deep tendon reflexes ("DTR") -- all symptoms he deems are "usually noted in patients with MS" (*id*. at 8).

Dr. Tenser acknowledges that while Petitioner's complaints in April 2011 would not suggest MS, he concedes that MS is "a very variable illness," and that symptoms among patients often differ. Ex. C at 3. Irrespective of that concession, Dr. Tenser opines that the normal brain MRI in April 2011 goes "very much against" an MS diagnosis at that time.[65] *Id*. Furthermore,

[65] In Dr. Steinman's fifth expert report, he rebuts this point from Dr. Tenser, stating that Petitioner's MRI of April 27, 2011, was done without contrast; he opines that *if* an MRI with contrast had been conducted at that time, then her MRI results "could certainly have demonstrated MS." Ex. 46 at 5. Dr. Tenser, in turn, counters that point in his rebuttal expert report, stating that, regardless of the fact that the MRI was done without contrast, "[a]bnormalities typical of MS were not seen" which still indicates an MS diagnosis was not medically appropriate at that time. Ex. EE at 3. Specifically, Dr. Tenser notes:

> I think it very unlikely for a contrast-enhancing brain lesion in MS to not be seen on standard nonenhanced T2 imaging, and the MRI of April 27, 2011 did not show T2 abnormality.

Dr. Tenser points out that, *even if* Petitioner's clinical neurology exam conducted on April 21, 2011, which yielded normal results, can be discounted because it was conducted by an emergency room physician and not a neurologist, her subsequent normal neurology exam conducted by her neurologist on June 10, 2011 (*see* Ex. 13 at 29), undercuts the conclusion that Petitioner had MS symptoms at that time. *Id.*

Additionally, Dr. Tenser points to Petitioner's normal results from her cerebrospinal fluid testing on May 18, 2011 (*see* Ex. 5 at 16), but acknowledges that "MS-related cerebrospinal fluid testing" was not performed at that time. Ex. C at 3.

While he acknowledges that Petitioner's "mild leg weakness" during her visit with a neurologist on July 1, 2011 could possibly be evidence of the onset of her MS, he discounts that possibility by pointing to other records around that time frame which make that possibility unlikely. *See* Ex. C at 3 (discussing Ex. 13 at 27). Specifically, he points to the fact that (1) her "coordination" and "DTR's" [deep tendon reflexes] were normal upon examination on July 1, 2011, and (2) that on her subsequent visit on August 12, 2011, weakness was not noted as a complaint at that time, deeming these as "early" neurological signs that are important in distinguishing MS from other conditions.[66] *Id.* Dr. Tenser also points to Petitioner's clinically normal neurology exam in August 2011 (*see* Ex. 22) as supportive of his position that the onset of Petitioner's MS was not in April 2011. *Id.*

Dr. Tenser summarizes Petitioner's non-specific symptoms and abnormal laboratory studies[67] in the spring of 2011, as possibly being the result of "inflammatory," and "collagen-vascular diseases" -- from Sjögren's syndrome and Lupus -- *i.e.*, both diseases for which Petitioner was being treated. Ex. C at 4. Additionally, he points out that Petitioner's medical records support her improvement with steroidal treatments, with deterioration of her condition when steroids decreased -- a clinical course of disease progression that, according to Dr. Tenser, is "much more typical [of an] inflammatory, collagen-vascular disease than MS." *Id.*

Dr. Tenser additionally opines that the combination of: (1) "clinically apparent leg numbness and weakness," (2) her brain MRI of April 27, 2012, reflecting abnormal and enhanced multiple white matter abnormalities, and (3) an abnormal cervical spinal cord MRI conducted on April 27, 2012, reflecting several lesions enhanced, all point towards Petitioner's onset of MS

Ex. EE at 3. In other words, Dr. Tenser opines that it would be very unlikely that Petitioner's MRI results of April 27, 2011 would not reflect lesions of the brain, if in fact such lesions existed. *Id.* Moreover, Dr. Tenser believes that when examined in the aggregate, Petitioner's medical condition in mid-April -- including the lack of typical MS symptoms in her neurological history, the lack of findings on a neurological exam, and the lack of brain MRI abnormalities of the type seen in MS patients -- also suggests she did not experience onset of MS in April 2011. *Id.* at 2-3.

[66] *See* Ex. 13 at 27, 23.

[67] Dr. Tenser specifically highlights the abnormal laboratory studies from April 2011 that reflected abnormal levels of ANA, SS-A, SS-B, and rheumatoid factor. Ex. C at 7. *See* explanation of those laboratory testing factors at n. 17 and 34, *supra*.

being sometime in the "spring of 2012," and not in April of 2011.[68] Ex. C at 4.

ii. General Causation Opinion

Dr. Tenser questions the applicability of Dr. Steinman's molecular mimicry theory in explaining how the HPV vaccination can lead to MS, opining that Dr. Steinman's theory is "superficially compelling." Ex. C at 5. He criticizes Dr. Steinman's theory as being "largely based on knowledge of the protein primary structure" (*i.e.*, a protein's linear amino acid sequence), but fails to take into account the secondary and tertiary structure of the protein. *Id*. at 6. He deems this failure to be key, stating that the three-dimensional geometric form of a protein "may be very significant for the nature of [an] immune response against the protein, and it may be more important than the primary structure." *Id*. In sum, Dr. Tenser considers molecular mimicry to be an interesting theory needing further investigation, but does *not* deem it to be compelling here because, in his view, it lacks substantive proof to explain how Gardasil can cause MS in general. Ex. C at 6.

Dr. Tenser also points to epidemiological studies that examined the association between vaccinations and MS ("the Langer-Gould[69] study), and the association between HPV vaccination and MS ("the Scheller[70] study"), as undercutting Dr. Steinman's general causation theory in this case.[71] He points out that those studies investigated a large population size to reach their

[68] Dr. Steinman's sixth expert report attempts to refute Dr. Tenser's opinion regarding the timing of Petitioner's onset of symptoms; however, he essentially reiterates his onset opinion stated in his first expert report, but does not add any specific points opposing Dr. Tenser's opinion. *See* Ex. 47 at 2 (Dr. Steinman stating "[i]n response to Dr. Tenser's timeline I really have nothing to add beyond what I have already written.").

[69] *See* Ex. C at 7 (Dr. Tenser citing Langer-Gould et al., *supra*, at n. 63, for the following proposition: "We found no longer-term association of vaccines with MS or any other CNS ADS [central nervous system acquired demyelinating syndromes], which argues against a causal association.").

[70] *See* Ex. C at 8 (Dr. Tenser citing Scheller et al., *supra*, at n. 9, for the following proposition: "qHPV [quadrivalent human papillomavirus] vaccination was not associated with the development of multiple sclerosis or other demyelinating diseases.").

conclusion that the Gardasil vaccination "does not increase the occurrence of MS." *Id*.

iii. Specific Causation and Appropriate Temporal Association

Dr. Tenser uses Dr. Steinman's own work on EAE to undercut Dr. Steinman's opinion that ninety days post-HPV vaccination is a medically appropriate time frame between Petitioner's administered HPV vaccine and her purported onset of MS. *See generally* Ex. C at 6. Dr. Tenser explains that EAE induced in mice is the "most commonly investigated immune model of MS," highlighting that even in the experimental literature where variables can be tightly controlled, investigators do *not* commonly suggest disease onset of EAE ninety days after immunization. *Id*. In fact, he states that "investigators typically do not report EAE more than *30 days* after immunization." Ex. C at 6, emphasis added. Further, Dr. Tenser argues that the "Gautam 1994" and "Gautam 1998" studies that Dr. Steinman submits as apparently supportive of his position in fact provide more support for Dr. Tenser's position on this point. Specifically, Dr. Tenser notes that the Gautam 1994 and 1998 studies, which notably are studies that Dr. Steinman also co-authored, did *not* find that EAE could occur after 30 days. *Id*. Instead, in those studies, Dr. Steinman and his co-authors stopped following mice *beyond 40 days*, thus implying that even the authors themselves did not believe that EAE occurred after that time. *Id*.

Dr. Tenser additionally opines that Dr. Steinman's argument regarding the precise meaning of onset for MS patients (*see generally* Ex. 35 at 1), is a "vague and unhelpful argument," even referring to that discussion as nothing more than a "straw-man argument." Ex. C at 6-7. As a counter to Dr. Steinman's point on this issue, Dr. Tenser states that the onset of Petitioner's MS was in April 2012 -- *i.e*., approximately 15 months after her Gardasil vaccination -- thus making a "causal relationship between Gardasil and the development of MS very unlikely." *Id.* In the alternative, Dr. Tenser states that, *even assuming* that Petitioner's onset of MS was in *mid-April*

[71] Dr. Steinman's fifth expert report attempts to refute Dr. Tenser's reliance on the Langer-Gould and Scheller studies by once again highlighting what he believes are flaws in those studies. *Compare* Ex. 46 at 1-4, with Ex. 35 at 27-29. In sum, Dr. Steinman believes that those two studies are flawed in various ways that do not make them appropriate proxies to the effects of the HPV vaccination on a US population. *See generally* Ex. 46. Dr. Tenser, in turn, counters in his rebuttal expert report, classifying these criticisms by Dr. Steinman as "very much a straw-man argument." Ex. EE at 1. He points out that "lesser sun exposure" is "currently the most MS-discussed environmental factor" that is associated with "greater frequency of MS." *Id*. He states that the Scheller study examined a Scandinavian population, "living in northern latitudes with less sunlight exposure, who would be at greater risk for developing MS," thus making the demography of the Scheller study even *more powerful* in its implications since "if no correlation of the HPV vaccine and development of MS were demonstrated for Scandinavians, it really goes against a putative correlation." *Id*. at 1-2. In attempting to refute Dr. Tenser's reliance on those two studies, Dr. Steinman's fifth expert report also veers into discussions about his legal opinions on the appropriateness of epidemiological studies in the Vaccine Program. *See* Ex. 46 at 1 ("Although epidemiology is important to guide public health decisions, it is problematic for the context of this court.").

2011, as opined by Dr. Steinman, onset approximately ninety days from vaccination, is still "too long," by Dr. Steinman's own research that he submits as supportive of his opinion. *Id*. at 8-9.

2. Harry Schroeder, M.D., Ph.D.

a. Qualifications

Dr. Schroeder received his Ph.D. in Cell Biology in 1979, and his medical degree in 1981, both from the Baylor College of Medicine. Ex. Q at 1. Dr. Schroeder completed his residency training in internal medicine at the University of Kentucky Medical Center, and completed his fellowship in Medical Genetics. *Id*. at 2. He became board-certified in internal medicine in 1984, and in clinical genetics in 1987. *Id*. at 4.

Dr. Schroeder started as an Assistant Professor in 1988, at the University of Alabama at Birmingham (UAB) in the Department of Medicine's Division of Developmental and Clinical Immunology. He has been a full Professor at that institution since 1998. Ex. Q at 2-3. He has concurrently held a faculty position at UAB's Department of Microbiology, where he has been a full Professor since 1998. *Id*. Dr. Schroeder has been the recipient of several National Institutes of Health (NIH) grants, has been a reviewer for well-renowned scientific journals, and has been a member of several prestigious professional medical societies. *Id*. at 4-23. His CV lists that he has co-authored over 95 peer-reviewed articles, and several book chapters and books. *Id*. at 24-33.

b. Medical opinion

i. Onset

Dr. Schroeder opines that more than a year after her Gardasil vaccination on January 19, 2011, Petitioner "developed a demyelinating disorder, most likely multiple sclerosis, that led to weakness and loss of neural function." Ex. P at 15. He additionally states that Petitioner did *not* have MS in mid-April 2011, and provided a snapshot of Petitioner's concurrent medical conditions at that time. *Id*. at 7. He highlights that Petitioner presented to the emergency room on April 21, 2011, with a complex picture reflecting -- (1) the "sudden onset of generalized weakness, arthalgias, lightheadedness, and confusion"; (2) laboratory testing demonstrating "an elevated ANA titer compatible with lupus," and an elevated SS-A and SS-B "compatible with Sjögren's syndrome"; (3) evidence of an ongoing inflammatory state due to an elevated ESR, and (4) "serologic evidence of recent exposure to *B. burgdorferi*, the cause of Lyme Disease" -- but that none of these suggest MS. *Id*.

Dr. Schroeder additionally points to the MRI performed in April 2011, noting that it did not disclose any evidence of demyelination. Ex. P at 7. Thus Petitioner's treating physicians did not entertain a MS diagnosis at that time. *Id*. In this regard, he explains the import of an MRI without contrast, noting this means that no "active MS lesions" would have been detectable at that time. Ex. BB at 3. He also critically points out, however, that while no active MS lesions would be detectable, an MRI without contrast would still reflect signs of demyelination, and her MRI in April 2011 showed "no indication on the test result that demyelination was observed." *Id*. In summary, while Dr. Schroeder admits that definitive MRI and lumbar puncture testing for MS was

incomplete in April and May of 2011, he points to other contextual evidence in the medical records and laboratory testing that provides a lack of clinical or diagnostic evidence of demyelination in the time frame surrounding Petitioner's first emergency room visit on April 21, 2011. *See generally* Exs. P and BB.

ii. General and Specific Causation Opinion

Dr. Schroeder opines that while he respects Dr. Steinman's expertise in conducting valuable experiments in the EAE model, he questions the applicability of his molecular mimicry theory in inducing MS specifically in Petitioner. Ex. P at 13.[72]

Moreover, Dr. Schroeder provides an alternative explanation for the cause of her initial symptoms in mid-April 2011, stating that those symptoms are more likely due to an inflammatory state caused by Petitioner's exposure to *Borrelia burgdorferi*, the bacterial species that causes Lyme Disease, rather her Gardasil vaccination. Ex. P at 7, 15. In sum, he opines that Petitioner's case is similar to most other cases of MS, in that the cause of her MS is simply unknown. *Id*. at 15.

iii. Appropriate Temporal Association

Dr. Schroeder opines that Petitioner's demyelination occurred more than a year after her Gardasil vaccination, indicating that there is no proximate temporal relationship between the HPV vaccination and the onset of her MS. He additionally posits that a temporal association between Petitioner's HPV vaccination and the onset of her MS is further unlikely due to her "intervening history of infectious and autoimmune inflammation," such as Lyme Disease, Lupus, and Sjögren's syndrome. Ex. P at 8. In other words, he explains that a temporal association between Petitioner's HPV vaccination and the onset of her MS more than a year later is simply medically unlikely when accounting for the complicated intervening medical history suffered by Petitioner during that time period.

V. APPLICABLE LAW

A. Petitioner's Overall Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed.

[72] In both of Dr. Schroeder's expert reports, he additionally discusses an aspect of Dr. Steinman's theory -- that MS is the result of an immune response to myelin basic protein (MBP). *See generally* Exs. P and BB. In his rebuttal expert report, after reviewing and discussing the previously unsubmitted medical records, Dr. Schroeder opines that his "overall opinions in this case remain unchanged," noting that while Dr. Steinman presents "an interesting and intriguing set of hypotheses regarding the etiology" of MS in Petitioner, he believes that "there is insufficient data to support" Dr. Steinman's hypotheses as it relates to her. Ex. BB at 10. Additionally, he believes that the "timing of the development of the demyelination makes it unlikely that the second [HPV vaccination] was the likely cause" of Petitioner's MS. *Id*.

Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873* (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records of by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*. *Althen* requires that petitioner establish by preponderant evidence that the vaccinations he received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." Id. at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs*., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility … in many cases may be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish

her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second Althen prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; Capizzano, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs*., No. 06-522V 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third Althen prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs*., 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon

common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88

Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).[73]

VI. ANALYSIS

A. Multiple Sclerosis (MS)

Multiple sclerosis (MS) is characterized as a chronic inflammatory, demyelinating disease of the central nervous system with an unknown etiology.[74] Ex. 41 at 16-17, ECF No. 45-2.

[73] Although I have considered the entire record, including the voluminous medical records and medical literature, in arriving at my decision, I will only discuss evidence specifically relevant to the resolution of this matter. *See Paterek v. Sec'y of Health & Human Servs.*, 527 Fed. Appx. 875, 884 (Fed. Cir. 2013). This includes medical literature submitted by both sides. *Id.*, at *884 ("Finding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered.")

[74] Dorland's characterizes MS, in relevant part, as follows:

According to the National Institute of Neurological Disorders and Stroke of the National Institutes of Health, MS is the most common disabling neurologic disease in young adults, appearing most often in individuals between the ages of 20 and 40 years old. The course of the disease is highly variable, where some individuals have minimal disability, whereas others suffer increasing disability over time. Approximately 400,000 individuals in the United States suffer from MS, with approximately 10,000 new cases diagnosed annually. Women are two to three times more likely to develop MS than men. *See* Ex. 41 at 16-17; Ex. P at 11-12.

B. Onset of Petitioner's MS

After a careful consideration of the entire record of this case, I find that the onset of Petitioner's MS symptoms was not in mid-April 2011; rather, I find that her onset of MS symptoms began sometime in late March 2012.

1. *Petitioner's MS Onset Was Not in Mid-April 2011 or in the Months Prior*[75]

Dr. Steinman points to some evidence that weighs in favor of an April 2011 onset; this includes Petitioner's symptoms of general weakness, distant affect, and malaise and fatigue reported on April 21, 2011.[76]

However, after reviewing all the evidence in this case, I find the medical record evidence, the contemporaneous assessments of Petitioner's treating physicians, and the opinions of Dr. Tenser and Dr. Schroeder to be more persuasive in explaining that Petitioner's MS onset was *not*

> [A] disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter; symptoms usually include weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term multiple also refers to remissions and relapses that occur over a period of many years.

Dorland's at 1680.

[75] My conclusion in this regard, that Petitioner did not have an onset of MS in mid-April 2011, or at an earlier point in time, is *not* changed by my careful consideration of the affidavits filed in this case. In forming my opinion on onset, I generally relied on the facts set forth in the contemporaneous medical records, as I find those records to be more reliable. *See Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (Fed. Cl. 1993) (holding that "[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later."). This is especially so since the record reveals that Petitioner filed an affidavit in this case alleging that her onset of symptoms started in early February 2011, whereas her affidavit filed in case number 14-212V (*see* Ex. A, ECF No. 25-1) alleged that the onset of her symptoms was after mid-March 2011. *See supra* at Section I(A) and Section II(B)(1)-(2).

[76] Also of note, in the Emergency Department records from April 25, 2012 Petitioner reports that "she was in her usual state of health up until 1 year ago when she started developing BLE numbness and tingling". While this may support onset in April 2011, none of the experts in this case elaborated on this specific point. I have considered this notation in determining the date of onset of Petitioner's symptoms, but find the evidence contrary to onset in April 2011 and in support of onset in March 2012 to be more persuasive.

in mid-April 2011, than Dr. Steinman's and Dr. Sy's opinions to the contrary. This is primarily so because Drs. Tenser and Schroeder thoroughly support their onset opinion by references to the relevant medical records, explaining and contextualizing Petitioner's complex medical conditions in the ensuing months starting from mid-April 2011. In contrast, I find Dr. Steinman's onset opinion to be cursory, in that it does not provide an analysis of Petitioner's medical history as a whole. Dr. Steinman only selectively discusses non-specific symptoms reflected in a few of Petitioner's medical records in the time period shortly after mid-April 2011, but fails to properly explain how those symptoms signify an onset of MS. This contrast in the degree of explanation becomes even more probative when one considers Petitioner's medical records, which reveal that in mid-April 2011 she was being treated for several other diseases, including suspected Lyme disease, Lupus, and Sjögren's syndrome, making it that much harder to precisely discern onset.

a. Discussion of Petitioner's Medical History Provided by Both Parties' Experts

Dr. Steinman primarily bases his onset opinion on three specific symptoms recorded in Petitioner's medical records that span over a week of her emergency room admission on April 21, 2011. He points to Petitioner's complaints of "general weakness," "distant affect," and "malaise and fatigue," but fails to explain how those non-specific symptoms amount to the onset of her MS at that time. *See* Steinman First Rep. at 3 and Steinman Fourth Rep. at 1-2.

In contrast, I find Dr. Schroeder's and Dr. Tenser's opinions that Petitioner did *not* have MS in mid-April 2011, to be far more persuasive as they provide a complete picture of Petitioner's complex medical condition during that timeframe. Their explanations reveal several critical points regarding Petitioner's condition.

For one, Dr. Tenser effectively explains that Petitioner's non-specific symptoms and abnormal laboratory studies in mid-April 2011 were likely the result of Sjögren's syndrome and Lupus, rather than MS. He points to Petitioner's medical records throughout 2011 and mid-2012 revealing that she was being treated for both of those diseases. He additionally points to Petitioner's improvement with steroidal treatments, and subsequent deterioration when steroids were decreased, as clinically more indicative of Sjögren's syndrome and Lupus, than MS. While Dr. Steinman acknowledges that Petitioner suffered from those two diseases, he does not address this point.

Second, Dr. Tenser points to four specific neurology exams conducted on Petitioner that do not reflect classical clinical symptoms of MS. Those clinical neurological exams were conducted on April 21, 2011 (Ex. 3 at 13); June 10, 2011 (Ex. 13 at 29); July 1, 2011 (Ex. 13 at 27); and August 12, 2011 (Ex. 13 at 23). In the aggregate, he points out that those four neurological exams do *not* reveal that Petitioner had classic symptoms of MS during that time frame.

Third, I find persuasive Dr. Tenser's and Dr. Schroeder's point that, while definitive MRI and lumbar puncture testing for MS was incomplete in April and May of 2011, other contextual evidence in the medical records and laboratory testing does not provide clinical or diagnostic imaging evidence of MS in that timeframe. In this regard, I note that Dr. Steinman does not effectively discount the brain MRI testing results of April 27, 2011, which revealed normal results.

While he states no contrast was given when Petitioner underwent that brain MRI testing, he provides no meaningful explanation as to *how or why* the use of contrast would have yielded different results. In contrast, Dr. Schroeder explains the implications of conducting an MRI without contrast, noting that this simply means that no *active* MS lesions can be detected on such an MRI, but that signs of demyelination can still be detected. As the brain MRI conducted on April 27, 2011 did not reflect signs of demyelination, he finds that to be evidence that Petitioner was not experiencing demyelination at that time. Moreover, Dr. Tenser explains that it would be "very unlikely" for a brain lesion in MS to not be seen on a "standard nonenhanced T2 imaging" -- *i.e.*, the type of brain MRI Petitioner underwent on April 27, 2011 -- if in fact such a lesion existed at that time. *See* Ex. EE at 3. Dr. Tenser additionally explains that, when examining, in the aggregate, Petitioner's condition starting in mid-April 2011 -- including the lack of typical MS symptoms in her neurological history, the lack of clinical findings on the multiple clinical neurology exams conducted during that time period, and the lack of brain MRI abnormalities of the type seen in MS patients -- *goes against* a conclusion that Petitioner's onset of MS was in April 2011. *Id*. at 3-4.

My finding that Petitioner developed MS in March 2012 is also strengthened by my close examination of the contemporaneous medical records from January 2011 through March 2012 during which Petitioner underwent numerous medical visits. In the aggregate, those medical records reflect that her treating physicians did *not* suspect/diagnose her with MS during that time frame, with a majority of those physicians in fact suspecting other causes for Petitioner's symptoms at that time, such as Lupus, Sjögren's syndrome, and/or Lyme disease.[77] *See, e.g.*, Ex. 3 at 13-21 (Tempe St. Luke's Hospital's emergency room records of April 21, 2011); Ex. 12 at 3-5 (Petitioner's consultation with her ENT specialist, Dr. Kelsch, on July 10, 2011); Ex. 4 at 2, 5-8 (Petitioner's consultation with her rheumatologist, Dr. Stuart Posner, on the following dates: May 17, 2011; June 9, 2011; July 8, 2011; February 6, 2012; and February 13, 2012); Ex. 13 at 23-31 (Petitioner's consultation with her neurologist, Dr. Wang, on the following dates: June 10, 2011; July 1, 2011; August 12, 2011; and November 22, 2011); and Ex. 5 at 50-51, 57-58 (Petitioner's consultation with her infectious diseases specialist, Dr. Schroeder, on the following dates: June 15, 2011; August 12, 2011; and December 13, 2011).

I additionally note that even Petitioner's primary care doctor during that time, Dr. Sy, did *not* contemporaneously suspect that Petitioner had MS, despite her retrospective representations to the contrary at Ex. 32, discussed in detail below. *See, e.g.*, Petitioner's visit with Dr. Sy on the following dates: April 22, 2011 (Ex. 2 at 22); April 25, 2011 (*id*. at 21); May 2, 2011 (*id*. at 20); May 4, 2011 (*id*. at 19); February 24, 2012 (*id*. at 18); and April 18, 2012 (*id*. at 17).

b. Dr. Sy's Letter Stating Her Beliefs as to Petitioner's Onset of MS

As previously noted, the record of this case additionally reflects a letter written by Petitioner's primary care doctor, Dr. Sy, dated March 5, 2015 (and thus after this case's initiation), in which she retrospectively reports that Petitioner began to have vague symptoms weeks after her HPV vaccination. Ex. 32 at 1. As support for her position, she references (1) a phone call notation

[77] The opinions of treating physicians are important in analyzing Vaccine Act cases and must be considered. *Andreu*, 569 F.3d at 1375.

from February 24, 2011, during which Petitioner called Dr. Sy for an ENT referral, and (2) a record from Petitioner's hospitalization on April 25, 2012, which purportedly "documents [Petitioner's] symptoms as starting 2 weeks after the Gardasil vaccine was given." *Id*.

For one, I note that Dr. Sy did not set forth in her written opinion any detailed explanation concerning why she believes that Petitioner's call for a referral to an ENT specialist marked the start of her symptoms. Second, as I note at footnote 38, above, an examination of the entirety of Petitioner's emergency department records starting on April 25, 2012 offer a different accounting of the start of her symptoms, as reported by Petitioner at that time. Those records reflect that Petitioner reported she "was in her usual state of health up until 1 year ago when she started developing BLE [bilateral lower extremity] numbness and tingling." Ex. 33-1 at 1; *see also* Ex. 33-1 at 41-43. Third, in direct contravention of Dr. Sy's onset statements in Ex. 32, even Petitioner's own expert, Dr. Steinman, does not opine in his expert reports that Petitioner's onset of MS started as early as a few weeks after Petitioner's HPV vaccination of January 19, 2011. *See* Ex. 35 at 1 (Dr. Steinman stating that Petitioner's onset of clinical symptoms of MS "began no earlier than mid-April 2011."); *see also generally* Exs. 35, 40, 42, 44, 46-47 (reflecting Dr. Steinman's first through sixth expert reports).

While I have given Dr. Sy's opinion letter careful consideration, in my final analysis, I find that her opinion is strongly outweighed by the rest of the evidence in the record concerning the onset issue, particularly the medical record evidence, the brain MRI results in April 2011 reflecting no demyelinating lesions (*see* Ex. 2 at 15-16), the thoracic and cervical spine MRI results in July 2011 also reflecting no demyelinating lesions (*see* Ex. 2 at 31 and Ex. 13 at 5-6), the contemporaneous assessments of Petitioner's treating physicians in the weeks and months after Petitioner's HPV vaccination, and the testimony of Dr. Tenser.

2. Petitioner's Onset of MS Was in Late March 2012

Upon my own close examination of the medical records, I find that Petitioner's medical condition drastically deteriorated over a short time period, starting in late-March 2012 to April 26, 2012, the date of her cervical spine MRI and brain MRI revealing findings worrisome/suspicious for demyelination. *See* Petitioner's relevant medical history from January 2012 through April 2012 discussed at Section II(A)(3).

a. Relevant Medical History from Late March to Late April 2012

Petitioner visited Dr. Wang on March 27, 2012, for complaints of headaches. Ex. 13 at 17-19. Dr. Wang noted that Petitioner has a medical history of lupus, and recorded Petitioner's descriptions of her headaches, which she described as causing "tingling and numbness in her extremities with her headache." *Id*. at 17. Upon examination, she was assessed as having "basilar migraine." *Id*. at 19.

Petitioner again visited Dr. Wang for her headaches on April 16, 2012. At that time, she reported that she was "having a new concern with numbness and tingling to the upper and lower extremities," which Dr. Wang deemed as being "consistent with peripheral neuropathy for upper and lower extremities." Ex. 13 at 15. Dr. Wang ordered additional testing to rule out certain

disorders, including electromyography (EMG) and nerve conduction velocity study (NCS) of the upper and lower extremities, and an MRI of the brain. *Id*. Petitioner had her EMG and NCS study done on April 23, 2012, which yielded normal results. *Id*. at 7.

On April 24, 2012, Petitioner presented for her consultation with Dr. Posner as a wheelchair-bound patient. Ex. 4 at 1. Dr. Posner noted that Petitioner "was last evaluated in this office on February 13, 2012 and her clinical condition has changed radically since that visit." *Id*. Upon examination, Dr. Posner noted that Petitioner's exam was "noteworthy for a disassociation between [her] affect being somewhat lighthearted compared to the profound motor difficulty" that she was experiencing at that time, especially in light of the fact that Petitioner was experiencing those symptoms "without obvious localizing neurologic signs." *Id*.

Petitioner presented to St. Joseph's Hospital's emergency department on April 25, 2012, being admitted to the neurology service with complaints of continued worsening of paresthesia and weakness in her bilateral lower extremity ("BLE") for the past month. Ex. 33-1 at 1. At that time, Petitioner reported that she "was in her usual state of health up until 1 year ago when she started developing BLE numbness and tingling." *Id*. Additional examinations were ordered to properly assess her care. *Id*. at 3.

Petitioner underwent an MRI of her cervical spine on April 26, 2012, which her neuroradiologist interpreted as reflecting "[f]indings worrisome for demyelination." Ex. 2 at 9. On that same date, Petitioner also underwent an MRI of her lumbar and thoracic spine, which both revealed unremarkable results. *Id*. at 11-12. She similarly underwent a brain MRI with contrast, the results of which were interpreted by her treating neuroradiologist as being "suspicious for demyelination." *Id*. at 13. A multiple sclerosis (MS) panel was tested on April 25, 2012; both the IgG index and the oligoclonal band study were listed as QNS.[78] Ex. 33-1 at 24.

b. Summary of My Finding

While the question of Petitioner's MS onset is not entirely straightforward in this case, I find that a preponderance of the evidence supports onset in March 2012 as opposed to April 2011. Upon analyzing the entire record of this case, with particular study devoted to the records above, Petitioner's complaints on April 25, 2012, of continued worsening of paresthesia and weakness in her BLE for the past month, puts Petitioner's onset of her MS symptoms around March 25, 2012. This finding is supported by a contextual analysis of Petitioner's visit with Dr. Wang on April 16, 2012, at which time she reported that she was "having a *new concern* with numbness and tingling to the upper and lower extremities." Ex. 13 at 15, emphasis added. In this regard, I also find Dr. Tenser's opinion on this issue to be persuasive in explaining that the combination of: (1) clinically apparent leg numbness and weakness noted in her medical records; (2) her April 2012 brain MRI reflecting abnormal and enhanced multiple white matter abnormalities; and (3) her April 2012

[78] Petitioner's medical records reflect that she was clinically diagnosed with MS by a Barrow NeuroImmunology neurologist on October 30, 2012, at which time Petitioner was noted to meet the 2010 McDonald's Criteria for MS based on her clinical history and radiologic progression. *See* Ex. 9 at 20.

abnormal cervical spinal cord MRI reflecting several lesions enhanced, in the aggregate, point towards Petitioner's onset of MS being sometime in the "spring of 2012." Ex. C at 4.

C. The Onset of Petitioner's Symptoms Did Not Occur in a Medically Acceptable Timeframe (*Althen* Prong Three)

More than a year passed from the date Petitioner received her HPV vaccination on January 19, 2011, to the onset of her MS symptoms around March 25, 2012. That timeframe from vaccination to onset is entirely too long. Even Dr. Steinman does not opine that onset of MS can occur outside the timeframe of mid-April 2011, much less more than a year after vaccination. Thus, I find Dr. Tenser's opinion (*see* discussion above at Section IV(B)(1)(b)(iii)) and Dr. Schroeder's opinion (*see* discussion at Section IV(B)(2)(b)(iii)) on this issue to be more persuasive, as compared to Dr. Steinman's opinion on this issue (*see* discussion above at Section IV(A)(2)(b)(iii).

Petitioner's medical history starting from mid-April 2011 also factors into my analysis. Specifically, I find Dr. Schroeder's position on this issue to be persuasive when he opines that a temporal association between Petitioner's HPV vaccination and the onset of her MS is further unlikely due to Petitioner's intervening history of Lyme Disease, Lupus, and Sjögren's syndrome. *See* Dr. Schroeder's discussion above at Section IV(B)(2)(b)(iii) and Ex. P at 8.

In the alternative, I note that *even if* I were to assume that the date of onset for Petitioner's MS symptoms is in mid-April 2011 (April 14, 2011), 86 days after she received her HPV vaccine, I still am not persuaded by Dr. Steinman's opinion that an almost three-month timeframe between Petitioner's HPV vaccination and the onset of MS is medically appropriate. I reiterate that the majority of Dr. Steinman's discussion regarding the basis of his timing opinion is of limited persuasive value, and serves to confound the issues when his explanations veer into discussions of questionable relevance.

I extensively discuss, in Section IV(A)(2)(b)(iii) above, the ways in which I find Dr. Steinman's timing opinion to be unpersuasive. My reasons include: (1) Dr. Steinman's propensity to improperly analogize study findings relating to different vaccines and different non-demyelinating diseases to his timing opinion in this case, without providing a cogent explanation as to *how or why* any of those studies can be analogized here; (2) his overstating the strength of certain literature as supportive of his position; (3) his veering into discussions of limited relevancy in his expert report, including providing his own legal opinion as to the appropriate standard in Vaccine Act cases; and (4) his selecting results from a study that supports his position, while ignoring the overall finding of that study. In short, Dr. Steinman's opinion on this issue lacks the foundational basis to explain how the HPV vaccination can trigger Petitioner's onset of MS three months after her vaccination.

In contrast, I find Dr. Tenser's opinion that, *even assuming* Petitioner's onset of MS was in *mid-April 2011*, as opined by Dr. Steinman, onset approximately ninety days from vaccination, is still "too long," by Dr. Steinman's own research that he submits as supportive of his opinion in this case. *See* discussion of Dr. Tenser's opinion regarding the appropriate temporal association at Section IV(B)(1)(b)(iii), above.

Furthermore, while I have carefully evaluated the specific arguments advanced by Dr. Steinman in this case, I generally note that special masters in the Program have consistently found the onset of demyelinating diseases to be temporally appropriate if symptoms begin within (but not after) eight weeks of vaccination.[79]

D. Remaining *Althen* Prongs

Because this claim can be resolved based on one of the *Althen* prongs, substantial additional discussion of the remaining two prongs is unnecessary. *See, e.g.*, *Lasnetski v. Sec'y of Health & Human Servs.*, 128 Fed. Cl. 242, 264 (2016), *aff'd*, 696 F. App'x 497 (Fed. Cir. 2017) (not error for special master to forego *Althen* analysis after determining that a petitioner had not in fact experienced the disease or illness alleged to have been vaccine-caused). I will, however, briefly note the following points relevant to the complete analysis. Petitioner's showing on the "can cause," first prong -- that the HPV vaccine can cause MS -- has both scientific reasonableness and plausibility, and was effectively supported by the literature filed as well as expert opinion offered. Dr. Steinman's expertise with central nervous system disorders and the field of immunology renders him well qualified to opine on the causal potential of vaccines in producing MS. There are also instances in the Vaccine Program in which other special masters have determined that a petitioner successfully established a plausible causation theory involving the capacity of different

[79] *See, e.g., Giannetta v. Sec'y of Health & Human Servs.*, No. 13-215V, 2017 WL 4249946 (Fed. Cl. Spec. Mstr. Sept. 1, 2017) (finding entitlement where MS symptoms occurred between 43 and 47 days after the vaccination); *Harmon v. Sec'y of Health & Human Servs*., No. 12-298V, 2017 WL 2872293 (Fed. Cl. Spec. Mstr. June 6, 2017) (finding entitlement where onset of a central nervous system demyelinating condition occurred 40 days after HPV vaccination); *Whitney v. Sec'y of Health & Human Servs.*, 122 Fed. Cl. 297, 309 (2015) (Judge Lettow reversing a special master's denial of entitlement on other grounds, but concurring with the special master's finding that petitioners had established a temporal association between their minor son's vaccinations and his onset of transverse myelitis (TM), which occurred seven to ten days after vaccinations); *Roberts v. Sec'y of Health & Human Servs.*, No. 09–427V, 2013 WL 5314698 (Fed. Cl. Spec. Mstr. Aug. 29, 2013) (finding entitlement where TM symptoms occurred four weeks post vaccination); *Bowes v. Sec'y of Health & Human Servs.*, No. 01–481V, 2006 WL 2849816, at *3 (Fed. Cl. Spec. Mstr. Sept. 8, 2006) (finding entitlement where TM symptoms occurred two weeks post vaccination); *Salmins v. Sec'y of Health & Human Servs.*, No. 11-140V, 2014 WL 1569478 (Fed. Cl. Spec. Mstr. Mar. 31, 2014) (granting entitlement where petitioner's onset of Guillain–Barré syndrome (GBS) occurred one week after vaccination); *Corder v. Sec'y of Health & Human Servs.*, No. 08–228V, 2011 WL 2469736, at *27–29 (Fed. Cl. Spec. Mstr. May 31, 2011) (denying entitlement partly based on a conclusion that petitioner's proposed four-month onset period from vaccination to GBS was too long; and concluding that two months is the longest reasonable timeframe for GBS to occur post vaccination); *Day v. Sec'y of Health & Human Servs.*, No. 12-630V, 2015 WL 8028393 (Fed. Cl. Spec. Mstr. Nov. 13, 2015) (finding entitlement where neuromyelitis optica (NMO) symptoms occurred three days after vaccinations); *Taylor v. Sec'y of Health & Human Servs.*, No. 13-700V, 2018 WL 2050857, at *22 (Fed. Cl. Spec. Mstr. Mar. 9, 2018) (finding the timeframe of approximately eleven weeks from the date of vaccination to petitioner's onset of Acute Disseminated Encephalomyelitis ("ADEM") to be "entirely too long" to be medically acceptable to establish a temporal association between her vaccination and ADEM); *Caruso*, 2017 WL 5381154 (denying entitlement where ADEM symptoms began two months post vaccination); *Rich v. Sec'y of Health & Human Servs.*, No. 12–742V, 2016 WL 3996334 (Fed. Cl. Spec. Mstr. June 30, 2016) (denying entitlement where ADEM symptoms occurred three months post vaccination), *mot. for review den'd*, 129 Fed. Cl. 642 (2016).

vaccines to cause MS, or similar demyelinating injuries. *See, e.g.*, *Taylor*, 2018 WL 2050857; *Giannetta*, 2017 WL 4249946.

At the same time, Respondent identifies weaknesses in the causation theory. In particular, Dr. Tenser offers compelling testimony that calls into question the extent of reliable scientific proof offered by Dr. Steinman to explain how Gardasil can cause MS in general. Dr. Tenser also points to epidemiological studies that examined the association between vaccinations and MS, and the association between the HPV vaccine and MS, as undercutting Dr. Steinman's general causation theory in this case. Because the case decisively turns on onset and timing, I need not decide conclusively if Petitioner carried her burden on this component of the *Althen* test -- although to the extent the evidence presented on this aspect of Petitioner's burden was close, I would necessarily have to decide it in Petitioner's favor. *See Althen*, 418 F.3d at 1280.

With regard to the second, "did cause," *Althen* prong, however several significant problems arise in the proof that lead me to state more unequivocally that Petitioner has not met this part of her evidentiary burden. First, Dr. Steinman provides a cursory discussion as to his specific causation opinion in this case -- *i.e.*, whether the HPV vaccination received by Petitioner on January 19, 2011 *did* cause her MS. While Dr. Steinman states that conclusion, he provides little analysis as to why that might be so in this case. The extent of his analysis rests on his own assertions that he conducted an analysis of the Gardasil package insert to reach his specific causation opinion. But he fails to provide any further elaboration of what exactly the analysis was that he conducted while examining the contents of that package.

Furthermore, the records from Petitioner's contemporaneous treatment providers do not support a causal link between the HPV vaccination and Petitioner's MS. *See* Section II(A)(2)-(4), above. My finding in this regard is further supported by my *Althen* prong three analysis; because the time between vaccination and onset of MS symptoms is not medically appropriate, I do not find that the vaccine *did cause* Petitioner's MS.

VII. CONCLUSION

Petitioner has unquestionably suffered a life-altering injury, and the affidavits credibly establish the suffering she and her family have experienced in its aftermath. But the Vaccine Act permits me to award compensation only if a Petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. In this case, the evidence advanced by Petitioner has fallen short of demonstrating such a link. Accordingly, I conclude that Petitioner in this case is not entitled to a Program award.[80]

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[80] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.